4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, 16, and 205

[Docket No. FDA-2020-N-1663]

RIN 0910-AH11

National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing national standards for the licensing of prescription drug wholesale distributors ("wholesale distributors" or "wholesale drug distributors") and third-party logistics providers ("3PLs"), as directed under the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act). Pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the DSCSA, the proposed rule would establish standards for all State and Federal licenses issued.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time on [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Electronic comments must be submitted

on or before that date. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions in the following ways:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-1663 for "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The title of this proposed collection is "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers."

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4261, Silver Spring, MD 20993, 301-796-3130. With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

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I. Executive Summary

A. Purpose of the Proposed Rule

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), includes provisions designed to strengthen the integrity of the pharmaceutical distribution supply chain. Among other measures, section 204 of the DSCSA amends section 503(e) of the FD&C Act (21 U.S.C. 353(e)), which requires licensure of prescription drug wholesale distributors (wholesale distributors or wholesale drug distributors or WDDs) and adds section 583 to the FD&C Act (21 U.S.C. 360eee-2), which requires FDA to establish by regulation national standards for the licensure of

prescription drug wholesale distributors. Section 205 of the DSCSA adds section 584 to the FD&C Act (21 U.S.C. 360eee-3), which requires licensure of third-party logistics providers and requires FDA to establish, by regulation, national standards for the licensure of third-party logistics providers.

This proposed regulation, when finalized, will establish the national standards for the licensure of wholesale drug distributors and 3PLs required under sections 583 and 584 of the FD&C Act, as amended by the DSCSA. As required by statute, the standards, terms and conditions for licensure established by this regulation will apply to both Federal and State licenses (503(e)(1)(B), 583(b), and 584(a)(1)(A) of the FD&C Act).

As discussed in section X (Federalism), section 585(b)(1) of the FD&C Act (21 U.S.C. 360eee-4(b)(1)) preempts States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act. However, the statutory provisions themselves do not establish these "standards and requirements"; instead, this regulation, once effective, will establish them. Accordingly, State and local licensure requirements will be preempted only once this regulation, when finalized, takes effect; until such time, current licensing of WDDs and 3PLs may continue. As discussed below, this determination will help avoid supply chain disruption, based on licensing uncertainties, during the period between DSCSA's enactment and the effective date of this regulation. Avoiding such interim period supply chain issues accords with Congress's overall intent to secure and strengthen the supply chain, as evidenced by other FD&C Act provisions added by DSCSA that recognize State licensure of WDDs and 3PLs prior to this regulation becoming effective.

In addition, pursuant to section 585(c) of the FD&C Act (21 U.S.C. 360eee-4(c)), regulation of areas within the historical police powers of the States would be unaffected by this regulation, including prohibiting employees of WDDs and 3PLs from engaging in criminal

activity related to prescription drugs, provided that the State requirements involved are not related to licensure of 3PLs or WDDs.

The requirements for state licensing of wholesale distributors are currently established under 21 CFR part 205, and FDA is now proposing the withdrawal of that regulation and for part 205 to be replaced with this proposed rule. Where a state from which a drug is being distributed has not established a licensing program in accordance with the regulation, the DSCSA establishes FDA as the licensing authority for wholesale distributor and 3PL licenses (sections 503(e)(1)(A)(i)(II) and 584(a)(1)(B) of the FD&C Act). When finalized, the national standards set forth in the proposed rule will provide greater assurance that these supply chain participants are sufficiently vetted and qualified to distribute products, further strengthening the supply chain and the safety of prescription drugs provided to American consumers.

When finalized, this proposed rule will also set forth the standards applicable to, and the requirements for approval of, third-party organizations involved in the licensure and inspection process ("approved organizations" or "AOs"). Sections 583(c) and 584(d)(2)(A) of the FD&C Act provide, respectively, that FDA may approve "third-party accreditation" or inspection services or programs to conduct inspections of facilities used by wholesale distributors seeking licensure and to review the qualifications of 3PLs for licensure. This proposed rule will also address the standards and requirements for approving such third-party accreditation or inspection services or programs.

Overall, this proposed rule is designed to ensure that the supply chain remains secure and that those prescription drugs subject to the DSCSA that are moving through the supply chain are properly stored, handled, and transported. These measures are intended to help protect American consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

For purposes of this proposed rule, FDA has defined "entity" or "entities" to mean a business organization, such as a corporation, company, association, firm, partnership, society, or joint stock company. Unless otherwise noted, the term "3PL" or "third-party logistics provider"

in this proposed rule includes both the 3PL entity and the individual 3PL facilities requiring a license.

B. Summary of the Major Provisions of the Proposed Rule

FDA is proposing to replace the current part 205 with a new part 205 that will implement the licensure requirements of the DSCSA and govern licensure of 3PLs and wholesale distributors. When finalized, the new part 205 will replace the existing part 205 in its entirety. Subpart A will set forth the national licensing standards for State and Federal licenses issued to 3PLs pursuant to section 584 of the FD&C Act, and subpart C will set forth the national licensing standards for State and Federal licenses issued to wholesale distributors pursuant to sections 503(e) (as amended) and 583 of the FD&C Act. Subparts B and D will set forth the applicable standards and processes for approved organizations to perform licensure reviews and conduct inspections.

1. National Standards for the Licensure of Third-Party Logistics Providers

The DSCSA identifies 3PLs as separate members of the drug supply chain—distinct from wholesale drug distributors—and specifically precludes States from regulating 3PLs as wholesale distributors (585(b)(2) of the FD&C Act). FDA is required by section 584 of the FD&C Act to establish national standards for the licensure of 3PLs, and the Agency is proposing those standards in subpart A of proposed part 205. When finalized, each facility of an entity meeting the definition of a 3PL in section 581(22) of the FD&C Act (21 U.S.C. 360eee(22)) will be required to be licensed by a State or Federal licensing authority in accordance with the standards articulated in subpart A of proposed part 205.

2. National Standards for the Licensure of Wholesale Drug Distributors

Prior to DSCSA's enactment, wholesale distributors engaging in interstate commerce were required to be licensed by the State in which they were operating pursuant to section 503(e)(2) of the FD&C Act (as then in effect). This section established minimum standards, terms, and conditions for licensing of wholesale distributors pre-DSCSA. As required by sections

503(e)(1)(B) (as amended by the DSCSA) and 583 of the FD&C Act, FDA is proposing to establish national standards, terms, and conditions through this rulemaking for the licensure of wholesale distributors that, when final, will apply to all State licensing programs as well as to the new Federal licensing program to be operated by FDA. These new standards would replace the previous standards set forth in current part 205.

3. Approval of Third Parties to Conduct Licensure Reviews and Inspections

In accordance with section 584(d)(2)(A) of the FD&C Act, FDA is proposing to establish a process by which third-party organizations will be approved by FDA to review a 3PL's qualifications for licensure. In addition, in accordance with section 583(c) of the FD&C Act, FDA is proposing to establish a process by which third-party organizations will be approved by FDA to conduct inspections of wholesale distributors for the purpose of licensure.

4. Conforming Changes

The regulation also proposes to amend 21 CFR 10.50(c) and 12.21(a)(2), which list statutory authorities that provide the opportunity for a formal evidentiary public hearing under 21 CFR part 12. Because the regulation proposes that wholesale distributors and 3PLs could request a formal evidentiary public hearing under part 12 for review of decisions affecting the denial, suspension, or revocation of 3PL or wholesale distributor licenses issued by the Secretary of Health and Human Services (Secretary), sections 503(e), 583, and 584 of the FD&C Act would be added to the list of statutory sections under which there is the opportunity for a hearing under §§ 10.50(c) and 12.21(a)(2), regarding such decisions. We are also proposing a conforming change to 21 CFR 16.1(b) to describe procedures for regulatory hearings that would add actions related to approved organizations under proposed §§ 205.19 and 205.33 respectively, including revocation or suspension of approval, to the list of actions for which a regulatory hearing under 21 CFR part 16 may be held.

C. Legal Authority

We are issuing this proposed rule under sections 301, 501, 502, 503(e), 582, 583, 584, 585, 701(a), and 704 of the FD&C Act (21 U.S.C. 331, 351, 352, 353(e), 360eee-1, 360eee-2, 360eee-3, 360eee-4, 371(a), and 374).

D. Costs and Benefits

In this rulemaking, we propose new national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers as directed under the Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act. If finalized, the rule would also establish a Federal licensing system for wholesale drug distributors and third-party logistics providers to use in the absence of a state licensure program that is consistent with the proposed national standards.

The standards for prescription drug wholesale distribution in the proposed rule would result in benefits to consumers and benefits to distributors from reducing the diversion of prescription drugs. Other monetized benefits include cost savings from reducing the frequency and quantity of licensure applications and cost savings from reducing state licensing standards in some states. We estimate that the annualized benefits over 10 years would range from $1.25 million to $31.50 million at a 7 percent discount rate, with a primary estimate of $10.66 million. We estimate that the annualized benefits would range from $1.26 million to $32.18 million at a 3 percent discount rate, with a primary estimate of $10.89 million.

We also expect that the proposed rule, if finalized, would impose costs on wholesale drug distributors, third-party logistics providers, states, approved organizations, and the Food and Drug Administration (FDA). Costs to wholesale drug distributors and third-party logistics providers include costs of learning about the rule, reporting to FDA, undergoing routine inspections, writing and revising standard operating procedures, and conducting background checks. Wholesale-drug distributors would also incur costs to furnish surety bonds to their state licensing authority to obtain or renew their licenses.

Costs to states include the time spent reading and understanding the rule, passing or revising the laws and regulations governing their licensure programs, and inspecting WDD and 3PL facilities. Approved organizations would incur legal, application, and training costs, as well as costs to inspect WDD and 3PL facilities. FDA costs include the costs to establish and operate a reporting database and a licensure program for wholesale drug distributors and third-party logistics providers and the costs to establish and operate an approval program for approved organizations.

We estimate that the annualized costs over 10 years would range from $13.21 million to $20.63 million at a 7 percent discount rate, with a primary estimate of $16.92 million. We estimate that the annualized costs over 10 years at a 3 percent discount rate would range from $12.83 million to $20.10 million, with a primary estimate of $16.47 million.

II. Table of Abbreviations/Commonly Used Acronyms in this Document

Abbreviation/Acronym	What It Means
3PL	Third-Party Logistics Provider
AO	Approved Organization
CFR	Code of Federal Regulations
DSCSA	Drug Supply Chain Security Act
DQSA	Drug Quality and Security Act
FDA or the Agency	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act

III. Background

A. Introduction

The DSCSA (Title II of Pub. L. 113-54) was signed into law on November 27, 2013, to better protect the U.S. drug supply chain. FDA's implementation of the DSCSA includes many activities, including this proposed rule. Once final, this rule will establish national standards for licensure of wholesale distributors and 3PLs, as required by the DSCSA. For information on additional FDA activities related to the DSCSA, a web page describing FDA's implementation activities can be found at: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm.

B. Need for the Regulation: the DSCSA and Establishment of National Standards for Licensure

The U.S. drug supply chain remains one of the safest in the world. However, the increasingly globalized nature of the supply chain brings with it complexities that increase threats to the safety and security of the U.S. drug supply. A breach at any point in the supply chain carries potential for dangerous, and even deadly, outcomes for American consumers.

In passing the DSCSA, Congress recognized the need for national standards for the storage, handling, and transport of prescription drugs and directed FDA, in sections 583(a) and 584(d) of the FD&C Act, to establish such standards by regulation for WDDs and 3PLs, respectively. These national standards will help diminish opportunities for dangerous and criminal conduct affecting the supply of prescription drugs in the United States. When final, every U.S. wholesale distributor and 3PL facility will be held to these standards through the statute's licensure requirements. Where a State does not have a licensing program in accordance with the regulation, FDA will be the licensing authority.

This proposed rule, when finalized, will provide much needed certainty and clarity for wholesale distributors and 3PLs seeking licensure. In passing the DSCSA, Congress believed the existing system of different regulation regarding supply chain security by each state created a patchwork system of governance and that a uniform national standard would address this concern. See statements of Senator Mikulski (Ref 1), Congressmen Mathis (Ref 2) and Congressman Latta (Ref 3).

Requirements for wholesale distributors currently vary significantly across State lines, and many wholesale distributors and 3PLs have facilities in multiple States. Specifically, State requirements and standards for licensure can vary on topics such as the length of time for which records must be maintained; qualifications of facility managers and designated representatives; facility requirements; licensure duration; renewal procedures; exemptions from the definition of wholesale distribution; and inspection and approval requirements by certain, specific organizations in order to receive licensure in certain States. This proposed rule, when finalized

will be an important first step in harmonizing these requirements, thus allowing for greater compliance and management of licensure.

Additionally, we note that commenters on FDA's draft guidance entitled "The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers" (Ref 4) agreed that creation of a uniform national standard for licensure, through the issuance of these regulations, should be the goal of FDA (see, e.g., Ref 5). Commenters noted that the patchwork of licensing standards was precisely the regulatory burden that the DSCSA was intended to eliminate. (see, e.g., Ref 6) Comments added that tracking and complying with different standards in different States on a continuing basis would be very time consuming and add unnecessary costs to the distribution chain (see, e.g., Ref 7).

We believe that the issuance of these regulations, when finalized, will provide far greater clarity to both States and regulated industry as to the requirements and expectations FDA has with respect to licensure. The publication of these regulations, when finalized, and the approach to preemption discussed in this document will reflect the national standard Congress intended, but will detail FDA's expectations with respect to licensure. This will allow for greater certainty in the logistics and distribution industry, and in the supply chain as a whole.

Since the passage of DSCSA, States have implemented disparate policies with respect to licensure of 3PLs. Some States repealed or eliminated 3PL as a licensure category, others are waiting for FDA to publish its regulations before determining how to proceed, some are licensing 3PLs under some other form of licensure, and some do not regulate 3PLs at all (Ref 8). These regulations, when finalized, will provide certainty and clarity in the logistics industry.

The Agency believes finalizing these proposed regulations is crucial to implementation of licensure of 3PLs as intended by DSCSA. Under section 582(a)(7) of the FD&C Act (21 U.S.C. 360eee-1(a)(7)), 3PLs are deemed licensed until the effective date of these regulations unless the Secretary has made a finding that the 3PL does not utilize good handling and distribution

practices and publishes notice thereof. Until these regulations are issued, and the framework for licensure established, the Agency cannot institute the provisions and the goals of DSCSA--to further secure the supply chain by including 3PLs as an authorized member of the supply chain through the licensure provisions, which will ensure that they are appropriately credentialed, inspected, and therefore duly qualified to participate in the supply chain.

Theft and diversion of prescription drugs continue to be major issues, contributing to drug shortages and creating significant financial losses, the effects of which cascade throughout the supply chain to consumers. FDA has observed that these instances often involve products distributed by unlicensed wholesale distributors. FDA standards, oversight, and regulations, including to implement the requirements of DSCSA, will lessen and hopefully eliminate product diversion in the legitimate supply chain. According to the National Association of Boards of Pharmacy (NABP)'s 2013 report entitled "Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply," drug diverters and bad actors seek out gaps in the distribution and regulatory structure, specifically seeking out States whose licensure framework is less stringent (Ref. 9). This proposed rule, when finalized, and the preemption of inconsistent State provisions will remedy this forum shopping for drug diverters who seek to take advantage of the lack of uniform framework.

Additionally, NABP's 2013 report also contends that the so-called "five percent rule" is a policy that has been ripe for exploitation due to the policy being inconsistently legislated, interpreted, and enforced from State to State. This was a policy under which FDA had previously concluded that sales of prescription drugs by a retail pharmacy to licensed practitioners for office use would be considered to be minimal and not constitute wholesale distribution, if the total dollar volume of these sales does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales (see further discussion in "Definitions" section below). However, this interpretation was not codified. The NABP observed that "pharmacies acting as wholesalers have been found to take advantage of the

parameters set by some States [regarding minimal quantities] when it comes to drug distribution. Rather than dispensing the drugs as mandated, these pharmacies retain them to resell to wholesalers at an amount exceeding the specified quantity of prescription medications as permitted in certain States (often times 5% of annual sales). Some have gone as far as to sell their entire inventory into the gray market" This proposed rule, when finalized, codifies the principle that the five percent rule only applies to pharmacy sales for office use. Sales above five percent for office use, or any sales to a wholesale distributor, require the pharmacy to become licensed and regulated as a wholesale distributor. This proposed rule will clarify this requirement and close a potential loophole that could lead to diversion of products and excessive sales from dispensers who are not licensed and registered as wholesale distributors when they are engaging in wholesale distribution.

Unlicensed wholesale distribution has been a major source of diverted products both leaving and reentering the supply chain. Significant amounts of drug diversion involve wholesale distributors, either diverting the product themselves from the supply chain, or purchasing product that was diverted by another actor. The DSCSA, which requires uniform national standards for licensure of wholesale distributors, will cut down on these types of instances of diversion since supply chain trading partners are required to transact with only other trading partners who meet the strict requirements laid out in these regulations. There are many examples of diversion and criminal action by wholesale distributors under the current regulatory scheme, which these regulations, when finalized, will discourage, or possibly even prevent, in the future.

As an example, from 2007-2014, individuals involved with the Minnesota Independent Cooperative bought prescription drugs from a network of illegal and unlicensed sources and sold approximately $393 million worth of diverted prescription drugs to wholesalers and retail pharmacies throughout the United States. These individuals falsified transactional documents, as well as licensure documents, to enter into fraudulent transactions with dispensers and other wholesalers. In a 2008 example detailed in the indictment, the unlicensed individuals involved

allegedly bought a truckload of stolen asthma inhalers for $662,000 and sold them through the Minnesota Independent Collective to another wholesaler for about $1 million (Ref 10). These regulations, when finalized, and the DSCSA requirements that trading partners only transact with authorized, licensed trading partners, and verify suspect and illegitimate product, will make these schemes far more difficult to achieve. Had DSCSA been the prevailing regulatory scheme at the time, other wholesale distributors and dispensers would have been deterred from doing business with the Minnesota Independent Collective because they were not an authorized trading partner.

In 2014, two individuals pleaded guilty to their involvement in a drug diversion and distribution scheme through an entity called Cumberland Distribution. Both defendants admitted that Cumberland Distribution purchased prescription drugs from individuals and entities that were not licensed to engage in the wholesale distribution of prescription drugs and were not authorized to distribute prescription drugs. Cumberland Distribution then distributed these products to dispensers. The prescription drugs were acquired through various networks of "diverters" who obtained prescription drugs from other unlawful sources. As a result, Cumberland Distribution could not lawfully resell the drugs. Pharmacies throughout the United States purchased these diverted prescription drugs from Cumberland Distribution under the guise that the products had been in the custody of licensed wholesale distributors or other authorized distributors since being sold by the original manufacturer (Ref 11). Under DSCSA, the licensure status of these purported wholesale distributors is easily searchable and verifiable, thus making diversion schemes, such as this, far more difficult to achieve. In addition to requiring FDA to establish national licensure standards, the DSCSA outlines critical steps for building an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States (section 582(g) of the FD&C Act). This system will enhance FDA's ability to protect American consumers from exposure to drugs that may be unfit for distribution and will increase efficiency in the detection and removal of potentially dangerous drugs from the U.S. drug supply chain.

The FD&C Act, as amended by DSCSA, requires FDA to establish national standards for the licensure of two critical members of the supply chain: wholesale drug distributors and 3PLs. It also requires that only those wholesale distributors and 3PL facilities licensed according to these national standards may engage in wholesale distribution or 3PL activities, respectively. Only licensed wholesale drug distributors and 3PLs whose facilities are so licensed will be considered "authorized trading partners" permitted under the FD&C Act, as amended by DSCSA, to engage in transactions related to the sale and distribution of certain prescription drugs with other members of the supply chain.

To create the standards proposed in the regulations, FDA conducted a comprehensive review of existing State standards for licensure including storing, handling, and holding prescription drugs, as well as other nationally recognized standards and model rules for wholesale distribution and logistics, such as those created by the NABP (Ref 12), Healthcare Distribution Alliance (Ref 13), World Health Organization (Ref 14), and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) (Ref 15). The Agency believes that the proposed standards align with existing practices and will help ensure that 3PL and wholesale distribution activities are undertaken in a manner that minimizes diversion and threats to the regulated supply chain.

C. Changes From the Prescription Drug Marketing Act (PDMA)

Prior to the DSCSA's enactment, the last comprehensive legislative action related to prescription drug distribution was the Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 100-293). Among other things, the PDMA required wholesale distributors to obtain licenses from States in which they were operating (sec. 6 of the PDMA; also see FDA's 2001 Report to Congress on the PDMA (Ref. 16)). Under the PDMA, FDA promulgated regulations that established minimum standards, terms, and conditions for licensure of wholesale distributors. The PDMA provided neither a specific definition of 3PL-type entities nor specific oversight over them; without a distinct regulatory framework for 3PLs, some States chose to regulate and

license 3PLs as wholesale distributors, with some others choosing to license 3PLs as separate entities. The DSCSA requires that all wholesale distributor and 3PL licenses meet the standards established by FDA (sections 503(e)(1)(B) and 584(a) of the FD&C Act), and that 3PLs not be licensed as wholesale distributors (section 585(b)(2) of the FD&C Act).

If an entity owns a facility in which it is engaging in 3PL activities and wholesale distribution out of the same facility, the entity will be required to hold a 3PL license and a separate wholesale distributor license for the distinct functions they perform.

IV. Legal Authority

The Agency is proposing this rule under the authority to propose national standards for the licensing of wholesale distributors and 3PLs granted to it by various sections of the FD&C Act, including sections 301, 503(e), 582, 583, 584, 585, 701(a), and 704 (21 U.S.C. 331, 351, 352, 353(e), 360eee-1, 360eee-2, 360eee-3, 360eee-4, 371(a), and 374).

Section 503(e) requires wholesale distributors to be licensed according to the standards, terms, and conditions established by the Secretary, and section 583 requires FDA to establish by regulation national standards for the licensure of prescription drug wholesale distributors. Section 584 requires 3PLs to be licensed according to standards established in regulations promulgated by FDA for the licensure of 3PLs. Section 301(t) prohibits the failure to comply with the requirements under sections 584 and 503(e). Section 301 also prohibits a number of actions concerning adulterated and misbranded drugs. Section 585 provides that states cannot implement licensing standards, requirements, or regulations that are inconsistent with, less stringent than, directly related to, or covered by the standards applicable under sections 503(e) and 584. Section 585 also precludes states from regulating 3PLs as wholesale distributors. To enforce these and other provisions of the FD&C Act, section 704 authorizes FDA to conduct inspections. Section 701(a) of the FD&C Act provides general authority to issue regulations for the efficient enforcement of the FD&C Act. By establishing national standards for the licensing of wholesale distributors and 3PLs, this rule, when finalized, is

expected to aid in the efficient administration and enforcement of the FD&C Act, and in particular would help efficiently enforce the provisions relating to licensure of wholesale drug distributors and 3PLs.

V. Description of the Proposed Rule

The national standards for the licensure of 3PLs, required by section 584 of the FD&C Act, as amended by DSCSA, are set forth in subpart A of proposed part 205. The national standards for the licensure of wholesale distributors, required by sections 503(e) and 583 of the FD&C Act, as amended by DSCSA, are set forth in subpart C of proposed part 205. The process and standards for third-party accreditation programs to become approved by the Federal Government to evaluate the qualifications of 3PLs for licensure, as required by section 584(d) of the FD&C Act, are established in subpart B of proposed part 205. The process and standards for third-party accreditation and inspection services to become approved by the Federal Government to conduct inspections of wholesale distributors, as permitted by section 583(c) of the FD&C Act, are set forth in subpart D of proposed part 205.

A. Scope/Applicability (Proposed §§ 205.1 and 205.2)

In accordance with section 584 of the FD&C Act, FDA is proposing to establish the national standards for licensing by State and Federal licensing authorities set forth in subpart A of part 205 that would apply to 3PL facilities in any State (see proposed § 205.1). Furthermore, in accordance with section 503(e)(1) of the FD&C Act, FDA is proposing to establish the national standards for wholesale distributors set forth in subpart C of part 205 that would apply to wholesale distributors of prescription drugs in any State (see proposed § 205.1). The standards, terms, and conditions for licensure established under part 205, subparts A and C, once finalized, would apply to all State and Federal 3PL and wholesale distributor licenses.

All 3PL facilities are required to obtain a 3PL license for each facility of such 3PL. The FD&C Act, as amended by DSCSA, prohibits States from regulating 3PLs as wholesale distributors. A 3PL that also engages in wholesale distribution in the same facility in which it

engages in 3PL activities must obtain a separate wholesale distribution license (see proposed § 205.1).

An entity is considered a wholesale distributor if the entity is engaged in the distribution of a drug subject to section 503(b) (relating to prescription drugs) of the FD&C Act (21 U.S.C. 353(b)), to a person other than a consumer or patient, with a few exclusions. Under section 201(g) of the FD&C Act (21 U.S.C. 321(g)), a drug includes a bulk drug substance, and under current FDA regulations, the term *bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances (21 CFR 203.3(e)). FDA believes that the distribution of bulk drug substances must have the same safeguards and provisions as the distribution of finished drug products. The same safeguards that prevent diversion and theft and secure the pharmaceutical distribution supply chain generally must include the transfer of bulk drug substances, as they are subject to the same concerns as the distribution of prescription drugs in finished dosage form.

FDA is proposing to establish the process and standards that would apply to any third-party accreditation or inspection services seeking to obtain or maintain approval by FDA to evaluate qualifications of 3PLs for licensure or to conduct inspections of wholesale distributors (see proposed § 205.1). Once finalized, proposed subparts B and D of part 205 would establish the process and standards for third-party accreditation and inspection services to become approved by the Secretary to review the qualifications of 3PLs for licensure, as required by section 584(d) of the FD&C Act, and to conduct inspections of wholesale distributors, as permitted by section 583(c) of the FD&C Act (see proposed § 205.2) (i.e., to become "approved organizations").

B. Definitions (Proposed § 205.3)

By its terms, the definitions of terms in section 581 of the FD&C Act (21 U.S.C. 360eee) applies in subchapter H. However, because those terms are also used throughout section 503(e) of the FD&C Act (as amended by the DSCSA), FDA considers the definitions and interpretations contained in section 581 of the FD&C Act to apply to those terms when used in proposed part 205. Specifically, the definitions of the following terms contained in section 581 of the FD&C Act apply when used in proposed part 205: affiliate, authorized, dispenser, illegitimate product, licensed, manufacturer, product, repackager, return, specific patient need, suspect product, third-party logistics provider, and wholesale distributor. In addition, FDA is proposing the definition of the following additional terms to help clarify the requirements. FDA believes that these proposed definitions align with existing law and regulations, as well as current industry practices.

- *3PL Activities*: Includes warehousing and "other logistics services" that are undertaken with respect to a product (as defined in proposed § 205.3(k)).
- *Change of Entity Ownership*: Recognizing that businesses often undergo changes in corporate structure through mergers, acquisitions, and other transactions, FDA proposes that "change of entity ownership" be defined to help ensure consistency with regard to how such changes will affect licensure. The definition describes the events that would constitute a change in ownership with respect to a partnership, unincorporated sole proprietorship, corporation, or limited liability company.
- *Co-Licensed Partner*: One of two or more entities that have entered into an agreement for the right to engage in the marketing of a prescription drug. The Agency believes this definition is in alignment with industry practice and existing laws.
- *Designated Representative*: An individual who is designated as the representative of the facility manager and, as such, is identified by the licensee as responsible for managing the daily operation of the establishment in compliance with licensure requirements and has the authority to implement corrective action when necessary.

This individual is also responsible for ensuring that personnel are appropriately qualified, assigned, and trained to accomplish their duties. The Agency believes this definition reflects current practices and understanding.

- *Entity or Entities*: A business organization, such as a corporation, company, association, firm, partnership, society, sole proprietorship, or joint stock company.
- *Facility*: A site at one general, permanent, physical location used to store or handle prescription drugs. For purposes of proposed part 205, a facility does not include a site, such as a corporate office or headquarters, where the sole activity conducted at the site is one of oversight, support, or business administrative function.
- *Key Personnel*: Any individual who has responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, designated representatives, and other individuals who are authorized to enter areas where prescription drugs are held and are likely to handle those prescription drugs as a part their responsibilities within the operation.
    - Section 583(b)(5) of the FD&C Act, as amended by DSCSA, requires that FDA establish standards for the "establishment and implementation of qualifications for key personnel" of wholesale distributors. These key personnel must be sufficiently qualified and screened to carry out the important responsibilities that come with positions within a wholesale distribution company. FDA believes individuals who hold these positions must be held to a high standard of qualification as they are entrusted with important aspects of protecting the pharmaceutical distribution supply chain.
- *Minimal Quantities*: An annual dollar volume of prescription drugs sold by a retail pharmacy to licensed practitioners for office use that does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales.

- Section 503(e)(4) of the FD&C Act excludes a number of activities from the definition of wholesale distribution. One excluded category, listed at section 503(e)(4)(E) of the FD&C Act, is "the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use." FDA has previously considered what constitutes minimal quantities in determining when the practices of a retail pharmacy become wholesale drug distribution and thereby subject to licensure (see 64 FR 67720, December 3, 1999). For example, in preamble discussions around codifying provisions related to wholesale distribution, FDA proposed a minimal quantities limit, considered comments, and ultimately concluded that sales of prescription drugs by a retail pharmacy to licensed practitioners for office use would be considered to be minimal and not wholesale distribution, if the total dollar volume of these sales does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales.
- The Agency continues to maintain its position that a 5-percent limit to what constitutes minimal quantities is sufficient "to meet the needs of licensed practitioners who may not purchase enough prescription drugs to go through a wholesale distributor and thus may not otherwise be able to easily obtain drugs for office use" (64 FR 67720 at 67748). We believe this standard is still relevant and is the industry standard. We note that in January 2013, the NABP passed a resolution that supports limiting the five percent rule to allow for transfer "between pharmacies, or from pharmacy to or from pharmacies to practitioners, only for the purpose of dispensing or administration, but not for resale; and to prohibit the transfer, distribution, or sale of prescription drugs from pharmacies to wholesalers for resale" (Ref 17). The transfer or sale from dispenser to dispenser for a specific patient need is already considered to not

be wholesale distribution under the FD&C Act (see section 503(e)(4)). This NABP resolution accords with FDA's proposed definition of *minimal quantities*. We request comment on the codification of this 5 percent limit for office use and of the definition of *minimal quantities*.

- Accordingly, a licensed retail pharmacy that distributes more than 5 percent of its annual sales to licensed practitioners is engaging in wholesale distribution, subject to all the requirements for wholesale distributors, unless its activities are otherwise excluded from the definition of wholesale distribution. The exemption for distributing minimal quantities of drugs by retail pharmacies to licensed practitioners for office use was "not created to confer a special benefit on retail pharmacies, but to meet the legitimate need of licensed practitioners" (64 FR 67720 at 67748). For purposes of section 503(e)(4)(E) of the FD&C Act, FDA is proposing to codify its position on "minimal quantities" in the proposed § 205.3(h) to mean the "total annual dollar amount sold to licensed practitioners for office use does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription drug sales."
- The Agency also notes that this exclusion only applies to sales of prescription drugs from licensed pharmacies to licensed practitioners for office use. FDA understands that some States and other entities have expanded the applicability of this exclusion from the definition of wholesale distribution to allow for distribution from pharmacies to other entities outside of licensed practitioners for office use, but FDA notes that this practice is not allowed under current Federal law. The statutory language at section 503(e)(4)(E) of the FD&C Act specifically limits the exclusion to the distribution of minimal quantities of a drug between a licensed retail pharmacy and a licensed practitioner for office use. Unless a specific sale or transfer of a drug from one

dispenser to another dispenser is outside of the definition of wholesale distribution because it is to a consumer or patient (e.g., to fulfill a "specific patient need," as defined at section 581(19) of the FD&C Act), a pharmacy that sells or trades prescription drugs to other pharmacies or other entities falls within the definition of wholesale distribution. Such activity is considered wholesale distribution under section 503(e)(4) of the FD&C Act, subject to all the requirements of wholesale distributors.

- *Other Logistics Services*: Services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a trading partner (e.g., manufacturer, wholesale distributor, dispenser), but that do not take ownership of the product or have the responsibility to direct a product's sale or disposition. It also includes services undertaken with respect to a product for a repackager that is acting on behalf of a manufacturer, wholesale distributor, or dispenser.
    - Under the DSCSA, the definition of 3PL includes entities that conduct "other logistics services" on behalf of a manufacturer, wholesale distributor, or dispenser of a product. The Agency recognizes that 3PLs may perform 3PL activities for repackagers and proposes to include in the definition of "other logistics services" those services undertaken with respect to a product for a repackager acting on behalf of a manufacturer, wholesale distributor, or dispenser.
    - Under this proposed definition, a common carrier that only transports a product, but does not take ownership of the product, is not conducting "other logistic services." Similarly, an entity that directs the sale or disposition of the product but does not take possession (such as a broker) would not be conducting "other logistics services" and does not meet the definition of a

3PL, but may be engaged in activities that meet the definition of a manufacturer or wholesale distributor.

- *Other Than a Consumer or Patient*: A person receiving the drug who is not (i) the individual identified as the recipient of the prescription drug, (ii) a dispenser fulfilling a specific patient need, or (iii) the clinical investigator, as defined in 21 CFR 312.3(b) (or any successor regulation).
    - FDA considers certain types of prescription drug distribution as outside the scope of "wholesale distribution" under section 503(e)(4) of the FD&C Act because they constitute "the distribution of a drug" to a "consumer or patient," which is excluded from the definition of wholesale distribution. The first of these is the distribution to, or receipt by, the patient, who, for purposes of DSCSA, FDA considers to be the individual intended to take or be administered the prescription drug. This would typically be the individual whose name appears on the prescription.
    - FDA also considers the transfer or sale of a drug from one dispenser to another to fulfill a "specific patient need" to be outside the scope of wholesale distribution. Specific patient need is defined at section 581(19) of the FD&C Act as "the transfer of a product from one pharmacy to another to fill a prescription for an identified patient." FDA would note, however, that a dispenser who transfers or sells a drug to a trading partner other than another dispenser, or to another dispenser where there is no specific patient need evidenced by a prescription, is distributing a drug to someone other than a consumer or patient, which, if not otherwise excluded under section 503(e)(4) of the FD&C Act, would be engaging in wholesale drug distribution requiring a wholesale distributor license.

- Finally, FDA considers the sale or transfer of a drug for investigational or research purposes to an investigator, as defined in 21 CFR 312.3 (or any successor regulation), under an investigational new drug application (IND) submitted to FDA to be outside the scope of wholesale distribution because the drug is used for in vitro, clinical, or other research purposes under an IND.
- For these reasons, FDA is proposing to exclude these types of transactions from the scope of wholesale distribution.

- *Product*: A prescription drug in a finished dosage form that is ready for administration to a patient without substantial further manufacturing (e.g., capsules, tablets, lyophilized products before reconstitution).
    - The definition of "product" proposed here is broader and more inclusive than that used for purposes of product tracing detailed in section 582 of the FD&C Act as defined in section 581(13). As used in section 584 of the FD&C Act for purposes of licensure of a 3PL, the term "product" excludes active pharmaceutical ingredients intended for incorporation into a finished drug product but have yet to undergo substantial further manufacturing to become the finished dosage form for administration. Of note, for purposes of section 582 of the FD&C Act (21 U.S.C. 360eee-1), the definition for "product" excludes certain types of prescription drugs in finished dosage form (section 581(13) of the FD&C Act).
- *Significant Disciplinary Action*: Any action by a State or Federal licensing authority that would limit or prevent a 3PL from conducting 3PL activities, or would limit or prevent a wholesale distributor from distributing or facilitating the distribution of prescription drugs. This includes suspension or revocation of a 3PL or wholesale distributor license, State controlled substances license, or Drug Enforcement Administration (DEA) registration, and potentially includes other disciplinary actions

such as a consent decree or final ruling of a State licensure board, depending on the impact on the 3PL's or wholesale distributor's legal ability to perform licensed activities.

- *Unfit for Distribution*: A prescription drug that has been identified as a drug whose sale would violate the FD&C Act. This definition includes prescription drugs identified as suspect or illegitimate (582(c)(4) of the FD&C Act); adulterated, including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity (section 501 of the FD&C Act); or misbranded (section 502 of the FD&C Act (21 U.S.C. 352)).
    - FDA believes that prescription drugs unfit for distribution must be segregated from those that are fit for distribution to protect patients from receiving potentially defective or harmful prescription drugs and prevent the distribution of drugs that are unfit for distribution.
    - A wholesale distributor or 3PL could potentially identify a prescription drug as unfit for distribution through their own examination of incoming and outgoing shipments of prescription drugs as outlined by proposed 21 CFR 205.12(c)(1) for 3PLs and 205.26(c)(4) for wholesale distributors, through inventory review under proposed 21 CFR 205.12(c)(4)(i) for 3PLs and 205.26(c)(5)(i)(B) for wholesale distributors, through other internal means designed to detect product that is unfit for distribution, or be notified of a prescription drug's status as unfit for distribution by a trading partner or others.
- *Wholesale distribution:*
    - Section 503(e)(4) of the FD&C Act defines wholesale distribution as "the distribution of a drug subject to [section 503(b) of the FD&C Act] to a person

other than a consumer or patient, or receipt of a drug subject to [section 503(b) of the FD&C Act] by a person other than the consumer or patient." The definition then goes on to list 19 activities that are not considered wholesale distribution. Of these, FDA is providing clarification about several that may be causing some confusion for industry and the States.

- Section 503(e)(4)(C) of the FD&C Act states that the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, does not constitute wholesale distribution. In addition to distribution of a drug during a declared public health emergency pursuant to section 319 of the Public Health Service Act, FDA considers the following circumstances to constitute emergency medical reasons and therefore be excluded from the definition of wholesale distribution: (1) the distribution of a drug to a first responder or other authorized individual administering prescription drugs to acutely ill or injured persons in an emergency situation and outside a healthcare facility, and (2) a long-term care facility receiving an emergency kit containing drugs for use in emergency situations to treat acutely ill or injured persons during hours of the day when necessary drugs cannot be obtained from a dispenser. Pursuant to 503(e)(4)(C) of the FD&C Act, this exclusion from the definition of wholesale distribution does not include distributing a drug during a shortage unless such shortage was caused by a public health emergency.
- The exclusion at section 503(e)(4)(E) of the FD&C Act for the distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use is discussed in the description of the term "minimal quantities."

- Section 503(e)(4)(H) of the FD&C Act excludes "the distribution of a drug by the manufacturer of such drug" from wholesale distribution. Therefore, FDA considers the activities of a manufacturer, as defined at section 581(10) of the FD&C Act, when distributing its own drug, as excluded from the definition of wholesale distribution and not subject to the requirements that apply to wholesale distributors. FDA believes this is supported by the term "wholesale distributor," which is defined at section 581(29) of the FD&C Act, in relevant part, as "a person (other than a manufacturer, a manufacturer's co-licensed partner . . .) engaged in wholesale distribution." The Agency notes, however, that if Manufacturer A purchases and distributes Manufacturer B's drug, for which Manufacturer A has no affiliation and is not a co-licensed partner, Manufacturer A is engaged in wholesale distribution, subject to all the requirements for wholesale distributors.

C. National Standards for Third-Party Logistics Providers

1. 3PL Licensure

3PL facilities are required to be licensed in order to conduct activities in any State (section 584 of the FD&C Act). As such, the proposed regulation provides that a 3PL facility may not conduct 3PL activities unless it is licensed by the State from which it conducts 3PL activities, or by FDA if the State from which 3PL activities are conducted has not established a licensure program in accordance with the regulations, as set forth in section 584(a) of the FD&C Act (see proposed § 205.4(a)). In addition, the requirement in 584(a) of the FD&C Act that each facility of the 3PL must be licensed, such that a 3PL with multiple facilities in a single State will have multiple licenses from that State, is set forth in proposed § 205.4(b).

Under FDA's proposed regulation, if a 3PL owns or leases a facility serving as a warehouse for products, the State in which the facility is located will be considered the State from which the 3PL "conducts activities" and will be the State from which the 3PL must obtain a

license for that facility under proposed § 205.4(a)(1). FDA understands there has been some confusion about whether an entity hired or contracted by another trading partner to provide labor, logistic, or administrative services for that trading partner in that trading partner's facility would be considered a 3PL. This could occur, for example, where a wholesale distributor hires a contractor to provide such support services from within the wholesale distributor's facility exclusively for that wholesale distributor. In this scenario, the contractor's activities from within the wholesale distributor's licensed facility would be captured by the wholesale distributor's license and obligations for compliance, and the facility would not be considered a 3PL or required to have a 3PL license. However, an entity that operates a facility in which it engages in wholesale distribution and performs 3PL activities on behalf of other trading partners for products it does not own or direct the sale or disposition of is required to obtain both a wholesale distributor and 3PL license for that facility.

Additionally, pursuant to section 584(a)(2) of the FD&C Act, if a product is distributed in interstate commerce, the 3PL must be licensed by the State into which the product is distributed if that State requires such license; however, section 584(a)(2) of the FD&C Act also provides that if the 3PL is licensed by FDA, as described in section 584(a)(1)(B), the 3PL is not required to obtain a license from the State into which the product is distributed (see proposed § 205.4(a)(3)). Finally, to ensure that a facility and those responsible for its operations meet the licensing standards, FDA proposes to require that 3PL licenses be facility- and owner-specific and not transferable to another establishment or owner (see proposed § 205.4(c)). 3PL licenses must be held at the licensed facility and must be made available to State, Federal, or other licensing authorities upon request (see proposed § 205.4(d)).

Section 584 states that the national licensing standards for 3PLs established by regulation take effect 1 year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act). National licensing standards for wholesale distributors established by regulation take effect 2 years after the date such final regulation is published (section 583(a) and (e)(3) of

the FD&C Act). For several reasons, including those discussed below, FDA does not intend to enforce the licensing requirements for 3PLs until 2 years after the final regulation is published.

FDA recognizes that 1 year may be insufficient time for States to implement 3PL licensure programs, should they decide to implement such a program, and for 3PLs to apply for licensure under these programs. Setting up a state licensure program may require additional time. This is especially true in States that will require State legislative action to implement a licensure program, with some State legislatures only meeting biennially.

Considering these factors, FDA does not intend to enforce these requirements with respect to the national standards for licensure until 2 years after the regulation is finalized. This will help ensure there is time for States to establish or modify their licensure programs in accordance with the new standards and time for 3PLs to apply and obtain a new license

For 1 year after the effective date of the final regulation, FDA also does not intend to enforce the requirements of section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act with respect to a manufacturer, wholesale distributor, dispenser, or repackager who has as a trading partner a 3PL that is not licensed, unless the 3PL is not licensed because the Secretary or a state licensing body has made a finding that the 3PL does not utilize good handling and distribution practices and has published notice thereof.

2. General Application Requirements for Licensure

The general requirements that must be met for a State or Federal licensing authority to issue a license to a 3PL facility are proposed in § 205.5. As proposed, § 205.5(a) includes requirements applicable to the individual who submits the application and states that the applicant must submit all required information and pay any applicable licensing fee to be issued a license.

The information that would be required as part of a 3PL's application for licensure of a facility is set forth in proposed § 205.5(b). FDA believes this information is necessary for the licensing authority to assess whether the 3PL is in good standing and has the infrastructure and

capabilities to fulfill its duties and obligations under these national standards for 3PL licensure. This includes disclosing whether the 3PL facility manager or designated representative has ever been convicted of a felony relating to prescription drug distribution (see proposed § 205.5(b)(7)). FDA believes that this information is crucial to protect the integrity of the prescription drug supply chain by ensuring that those responsible for the daily operations of a 3PL facility do not have a history of violating the FD&C Act. In addition, in its application for licensure renewal, under proposed § 205.7, a 3PL would be required to certify that the 3PL facility has continually met the requirements of § 205.5 and will inform the licensing authority of certain changes to information if such changes have not already been submitted to the licensing authority (see proposed § 205.5(c)).

3. The Federal Licensure Process

Section 584(a)(1)(B) of the FD&C Act gives FDA the authority to license 3PLs directly if the State from which a 3PL conducts 3PL activities has not established a licensure requirement in accordance with the regulations. The process that FDA will use for issuing licenses to 3PLs is detailed in proposed § 205.6. While § 205.6 is only applicable to 3PLs obtaining a license from FDA, FDA suggests that States implement similar procedures. FDA intends to help stakeholders understand who the appropriate licensing authority is in the 3PL's State.

The FDA licensure process begins when a 3PL seeking licensure for a facility submits an application to FDA for review and consideration (see proposed § 205.6(a)). The DSCSA permits FDA to approve third-party organizations, referred to as approved organizations or AOs, to evaluate a 3PL's qualifications for licensure (section 584(d)(2)(A)-(B) and 584(e) of the FD&C Act). If FDA has approved one or more organizations to review a 3PL's qualifications for licensure, a 3PL should note the AO it prefers on its application. FDA generally intends to review a 3PL's qualifications for licensure only if the review cannot be completed by an FDA-approved AO. The licensure review consists of a review of all documents submitted in support of the application and an inspection of the facility pursuant to proposed § 205.16. FDA intends for

the licensure application process to be electronic (see proposed § 205.6(a)) and to leverage existing technologies to streamline the licensure process.

While the DSCSA permits AOs to review a 3PL's qualifications for licensure and to recommend to FDA whether a 3PL should be licensed, the responsibility for determining whether a 3PL meets all applicable requirements and to issue the license remains with FDA (see proposed § 205.6(b)).

So as not to delay the licensure process, when reviewing an application, FDA intends to work with 3PLs to correct minor errors made on the application and communicate with the 3PL about additional information the Agency may need (see proposed § 205.6(c)). When FDA determines that a 3PL facility meets the applicable requirements and that none of the prohibited factors listed in proposed § 205.9(a)(1) are present, FDA will send the applicant an approval letter and a licensing certificate, effective on the date it is issued (see proposed § 205.6(d)).

FDA recognizes that a 3PL may have concerns about what happens to the status of its license if the AO that reviewed its qualifications for licensure has disciplinary sanctions taken against it that affect its approval status or if it is otherwise no longer considered an approved AO. While a 3PL facility should not be penalized for the actions of the AO that reviews its qualifications for licensure, FDA must ensure that the AO's review and findings provide a reliable basis for licensing decisions.

As such, FDA is proposing that the approval status of the AO that performed the licensure review for a 3PL facility will not automatically affect the licensure of a licensed 3PL facility that is otherwise in good standing (see proposed § 205.6(e)). Rather, in the event that an AO has disciplinary sanctions taken against it, ends its business, or is otherwise no longer considered an approved AO, the license of any 3PL facility reviewed by that AO will be subject to appropriate action in accordance with § 205.9 and other applicable statutes or regulations. FDA may verify the 3PL's compliance status and review the facts in that situation to determine the potential effect, if any, on the licensure of 3PL facilities reviewed by that AO.

FDA intends to publish additional guidance regarding the process and procedures related to obtaining and maintaining a 3PL license issued by FDA.

4. Changes to Information, Location, or Ownership of a Licensed 3PL

For the licensing authority to effectively carry out its responsibilities, a 3PL must keep its license information current and report any changes in information, including those that may significantly affect operations such as changes in location or ownership, to the licensing authority. Presently, the reporting requirements for these types of changes vary by State. FDA is proposing in § 205.7 that changes to certain information, including, for example, any changes in information submitted as part of an application for licensure, be submitted electronically to the licensing authority within 30 calendar days of the change (see proposed § 205.7(a)). Additionally, because a license is facility- and-owner specific (see proposed § 205.4(c)), the Agency is proposing that changes in the location or the ownership of a facility will require a new license (see proposed § 205.7(b) and (c)).

5. Expiration and Renewal of Licenses

The DSCSA requires that the regulations establishing national standards for 3PLs provide that a 3PL license expires 3 years after the date of issuance, with the option for renewal for additional 3-year periods (section 584(d)(2)(H) of the FD&C Act). FDA is proposing to implement this requirement under proposed § 205.8 by saying that all 3PL licenses, whether newly issued or renewed by the licensing authority, expire 3 years from the date of issuance or renewal. FDA also proposes that 3PLs may not submit renewal applications more than 90 days prior to the license's date of expiration to ensure that licenses are renewed based on current information. While we do not anticipate lengthy administrative delays by the licensing authority, if a 3PL files an application for a license renewal within the appropriate time period and there is an administrative delay reviewing the license application that causes the 3PL license to lapse, the 3PL will not be penalized for that administrative delay. In this scenario, the 3PL's license will be considered valid during the period of the administrative delay (see proposed § 205.8).

The Agency understands that at the time a final rule covering these proposed national standards goes into effect, there are likely to be 3PLs with existing licenses under State law. Nevertheless, 3PLs with existing State licenses must obtain new licenses in accordance with section 584(a) of the FD&C Act. These national licensing standards serve an important function of ensuring consistency across the domestic market. However, as described above, FDA does not intend to enforce the requirements with respect to the national standards for licensure of 3PLs until 2 years after the regulation is finalized. FDA's proposed requirements are further detailed in proposed § 205.16, which discusses the required inspections prior to licensure.

6. Licensure Denial, Suspension, Reinstatement, and Revocation -- Notice and Opportunity to Request a Hearing

The standards for licensure denial are set forth in proposed § 205.9.

Proposed § 205.9(a)(1) enumerates 9 circumstances under which the licensing authority would be required to deny a 3PL's request for licensure or license renewal. FDA believes that this list will help 3PLs focus on good storage practices outlined by FDA that are necessary to protect the integrity of the products in the pharmaceutical distribution supply chain. To avoid denial or delays of their applications, 3PLs should ensure that they address the reasons for denial of a license outlined in proposed § 205.9(a)(1) when they file for licensure.

Proposed § 205.9(a)(2) details the process afforded to 3PLs whose applications for licensure have been denied. FDA is proposing to provide applicants with the opportunity to provide additional information for reconsideration of the denial. If the licensing authority denies a 3PL's request for licensure after reconsideration, the 3PL will receive a notice of opportunity to request a hearing under existing FDA hearing procedures. FDA requests comment regarding the reconsideration and appeal process outlined in this regulation for 3PLs whose applications for licensure have been denied.

The proposed standards for suspending a 3PL license are set forth in § 205.9(b) and (c) and are based on the severity of risk posed to the public health. Under most circumstances, we

anticipate that a 3PL would have the opportunity for a hearing before licensure suspension. However, under certain circumstances that involve repeated conduct detrimental to the public health or refusal to correct significant issues that could lead to the dissemination of illegitimate product, the Agency may suspend a license immediately while giving the 3PL an opportunity to request a hearing. Under proposed § 205.9(b), a 3PL's license may also be suspended after the 3PL receives a notice of opportunity to request a hearing. A suspended 3PL must cease all 3PL activities until their license is re-instated. This provision applies when the licensing authority has a reasonable belief that the 3PL is not in compliance with licensure requirements. FDA is proposing for § 205.9(b) to require the licensing authority to notify the 3PL in writing of the intent to suspend its license. A 3PL will have 30 days from the date listed on the notice of intent to suspend a license to provide additional information to the licensing authority so it may reconsider its decision.

If reconsideration is not sought or is denied, the licensing authority will inform the 3PL in writing of its formal intent to proceed with license suspension. The notice will contain a statement informing the 3PL that it can request a hearing on the question of whether there are sufficient grounds for suspension. The 3PL will have 10 days from the date on the notice to inform the licensing authority of its intent to request a hearing; otherwise the opportunity for a hearing will be waived and the license suspended. FDA believes this process will afford 3PLs a sufficient opportunity to present information and attempt to remedy noncompliance issues which may threaten the safety of products in the supply chain. FDA requests comment regarding this reconsideration and appeal process.

Proposed § 205.9(c) allows for license suspension prior to opportunity for hearing and effective immediately if the 3PL's noncompliance poses an imminent threat to public safety. For example, if a 3PL is warehousing or shipping illegitimate product, and once made aware, corrective actions to protect the public health from the threat of these products are not taken, the 3PL's license could be suspended immediately. Another example could be a scenario where the

conditions under which drugs are held or warehoused cause the product to be illegitimate and the 3PL refuses to correct the conditions or continues to ship these illegitimate products. Under the proposed regulation, in such a situation, the licensing authority will inform the 3PL in writing that its license is suspended. The notice will also contain a statement informing the 3PL that it may request a hearing and that a hearing, if granted, will be afforded within 10 days upon the receipt of the 3PL's request for hearing. The 3PL has 10 days from the date on the notice of suspension to request a hearing; otherwise its opportunity for a hearing will be waived. FDA believes that this limits the amount of time a 3PL license would be suspended while providing a reasonable amount of time both for the 3PL to review the notice of suspension and collect the necessary information to demonstrate that its license should not be suspended, and for FDA to consider a request for a hearing and to schedule and prepare for a hearing, if the hearing request is granted. FDA believes immediate suspension of a 3PL license is crucial in cases where continued operation of the 3PL presents an imminent threat to public safety and the pharmaceutical supply chain.

Under proposed § 205.9(d), a 3PL's suspended license may be reinstated if the 3PL can demonstrate to the licensing authority that it is in compliance with regulation requirements.

Under the proposed rule, the process outlined at 21 CFR 10.75 is the default for appeals regarding a denied application for a 3PL license, and the hearing process outlined at 21 CFR part 16 is the default for appeals regarding a suspended or revoked 3PL license. However, the 3PL may request any of the procedures in 21 CFR parts 10 through 16. FDA believes that this proposed approach is consistent with current practice and suggests that States develop comparable processes.

The standards for revoking a 3PL license are set forth in proposed § 205.9(e). The licensing authority will revoke a license if it finds that a 3PL whose license has been suspended is unable or refuses to comply with the licensing requirements. The requirements governing the revocation of a 3PL license are set forth in proposed § 205.9(e)(2) through (5) and mirror those

outlined in § 205.9(b)(2) through (7) for licensure suspension, with one exception: when the licensing authority informs the 3PL of its intent to revoke a license, the 3PL is given no opportunity for reconsideration since it already had an opportunity to rectify deficiencies while its license was suspended.

In addition, where a 3PL fails to timely renew its application, the license will be considered expired and a 3PL will need to submit an application for new licensure because the licensing authority may be unable to confirm that the 3PL continues to meet all necessary licensure requirements (see proposed § 205.9(f)).

FDA is also proposing to terminate a 3PL's license upon request from the 3PL when the request includes a notice of the 3PL's intent to discontinue its activities and a waiver of an opportunity for a hearing. The 3PL will be required to apply for a new license should it decide to resume 3PL activities (see proposed § 205.9(g)).

7. Good Storage Practices for 3PL Facilities

The DSCSA charges FDA with creating national standards for the licensure of 3PL facilities, including the requirement that 3PLs comply with storage practices as determined by the Secretary (see section 584(d)(2)(C) of the FD&C Act). Those requirements are detailed in proposed § 205.10. FDA considers the requirement that "each facility of such [3PL]" be licensed "in accordance with the regulations" (section 584(a) of the FD&C Act) to mean that 3PLs without a facility are not required to be licensed. Section 584 of the FD&C Act provides that FDA will establish licensure standards that include requirements relating to storage of product. These standards address issues regarding access and maintenance that presuppose the existence of a physical facility where product is maintained. As such, the requirements apply to each 3PL facility that is owned, rented, or leased by the 3PL. If the 3PL shares the same name and location as another trading partner (for example, a wholesale distributor), each entity must be separately licensed and must have separate systems and processes in place for their separate functions (see proposed § 205.10(b)).

The requirements for 3PL facilities regarding how products will be stored and adequate security maintained are set forth in proposed § 205.10(c). This provision includes requirements for storage of nonsaleable products within the 3PL facility. If the facility is in possession of a suspect product, the facility must have clearly defined areas in which to quarantine the suspect product until the product is dispositioned (section 584(d)(2)(C)(i) of the FD&C Act).

FDA is also proposing to require that 3PLs keep illegitimate product and other products unfit for distribution in a clearly defined and designated area, separate from saleable products, until dispositioned so the illegitimate or otherwise unfit product is not inadvertently combined with saleable products (see proposed § 205.10(c)(2)). An illegitimate product poses as great a risk to public health, if not a greater risk, as a suspect product because a product is illegitimate when there is credible evidence shows that the product is counterfeit, diverted, stolen, intentionally adulterated such that the product would result in serious adverse health consequences or death to humans, is the subject of a fraudulent transaction, or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans (section 581(8) of the FD&C Act). As such, it is counter to public health to store products that are unfit for distribution alongside saleable product. Furthermore, it would be illogical to move suspect product that has been determined to be illegitimate out of quarantine and into another area to be potentially stored with saleable product.

8. Personnel Requirements Necessary for Good Storage Practices

Ensuring that 3PL personnel are appropriately qualified is integral to establishing good storage practices (section 584(d)(2)(C) of the FD&C Act). For this reason, proposed § 205.10(b)(3) requires that a 3PL facility must be designed in such a manner that only personnel who possess appropriate and verifiable experience and training will have access to areas in which products are held. While not proposed to be required in part 205, FDA believes that a best practice in order to maintain the security of prescription drug products, would be for a 3PL to screen personnel who work in areas of its facility where prescription drug products are held for

records of Federal or State criminal convictions relating to the possession, control, or distribution of prescription drugs. While also not proposed to be required in part 205, FDA believes it would be a best practice for a firm to request that employees state that they are not engaged in and will not engage in the illegal use of controlled substances while serving in their capacity within the 3PL.

FDA also proposes requiring that 3PLs maintain and make available to the licensing authority certain information about their facilities' managers and designated representatives (see proposed § 205.11). Furthermore, FDA is establishing specific employee qualifications with respect to facility managers or designated representatives that are necessary to effect good storage practices (see proposed § 205.11(b)). Specifically, FDA is proposing to require that a facility manager or designated representative of the facility manager serve in either capacity for only one facility at any one time (see proposed § 205.11(b)(2)). FDA believes that a facility manager or designated representative of the facility manager must be accountable for all operations of a 3PL facility. That facility manager or designated representative must be present within the facility, and must be familiar with the day-to-day operations of that facility. FDA believes that the best way to ensure the accountability and familiarity required for compliance is for a designated representative or facility manager to serve only one facility at a time. This is to ensure that the facility manager or designated representative is actively engaged in managing the daily operations of the facility and that they remain aware of any non-compliance issues that may arise. To ensure the qualified designated representative can fulfill their obligations to manage and carry out daily operations, FDA proposes to require that a 3PL provide its designated representative with adequate authority and the necessary resources (see proposed § 205.11(c) and (d)). FDA believes that establishing these requirements will help ensure that the products handled by a 3PL are properly safeguarded to protect the supply chain and the public health.

Section 584(d)(2)(E) and (F) of the FD&C Act requires mandatory background checks for facility managers or the designated representatives of facility managers to ensure that neither

the 3PL's facility manager nor the designated representative has engaged in the prohibited behaviors outlined in proposed § 205.11(e). Additionally, FDA is outlining other activities which may lead to the denial of licensure in proposed § 205.11(f). They are not bars to licensure, but they are factors that may be considered by licensure authorities when reviewing an application for licensure to determine whether the 3PL has storage practices sufficient to maintain adequate security over the facility. FDA requests comment on this section of the regulation and the scenarios outlined therein.

Requiring that individuals with significant authority over 3PL activities be subject to a criminal background check adds an additional layer of safety and security to the supply chain (see proposed § 205.11(g)). Theft of product by personnel who have direct access to areas where products are stored is a known problem across the healthcare industry; the background checks required by section 584(d)(2)(F) of the FD&C Act that FDA is proposing here are necessary precautions to prevent the potential theft, loss, or abuse of prescription drugs.

FDA suggests an additional best practice for a 3PL to utilize when staffing their operation. This best practice, related to staff who work within a 3PL, is designed to ensure security within a 3PL. FDA recommends to 3PLs that the individuals who work within their operation and have access to prescription drugs should not have a record of criminal activity involving violations of the FD&C Act or other laws involving prescription drugs.

When screening personnel who work in areas of a 3PL facility where products are held, including the facility manager or designated representative, FDA recommends that a 3PL consider whether such personnel have (1) engaged in a pattern of violating the requirements of section 584 of the FD&C Act that present a threat of serious adverse health consequences or death to humans; (2) been found to have committed or facilitated commission of any prohibited acts under the FD&C Act or violated or facilitated any violations of any of the regulations in this part or analogous provisions of the State licensing authority, as applicable; (3) been convicted of any violation of Federal, State, or local laws relating to drug samples, wholesale or retail drug

distribution, distribution of controlled substances, or third-party logistics services; or (4) been convicted of any felony under Federal, State, or local laws involving or related to prescription drugs. FDA believes that 3PLs should consider an applicant's history of violations of the FD&C Act, or other laws involving prescription drugs, when making staffing decisions.

9. Required Written Policies and Procedures

Section 584(d)(2)(C)(iii) of the FD&C Act enumerates certain types of written policies and procedures that FDA regulations must require, and tasks FDA with defining the content with more specificity. Those written policies and procedures are set out in proposed § 205.12. All 3PLs would be expected to establish, maintain, and follow the written policies and procedures set forth in these proposed subsections for each 3PL facility, to the extent that the requirements of those sections are relevant to the scope of their specific 3PL activities. Under the proposed regulation, all written policies and procedures will be made available to the licensing authority upon request, and the licensing authority will be permitted to have access to and copy records of the 3PL to ensure that the 3PL facility is following its written policies and procedures (see proposed § 205.12(a)). Written policies and procedures include those that are stored and maintained electronically.

FDA is implementing the statutory requirements listed in section 584(d)(2)(C)(iii) of the FD&C Act through proposed § 205.12(c)(1) through (6). Under these requirements, 3PLs must maintain written policies and procedures to address a product's receipt, security, storage, inventory, shipment, and distribution. Proposed § 205.12(c)(1) through (6) details the specific elements that such written policies and procedures must contain. Such elements are necessary to maintain supply chain integrity and align with current industry practices to protect the integrity of the drugs that are distributed through the supply chain.

To ensure good storage practices, FDA is also proposing to require that 3PLs establish written policies and procedures for handling not only expired product as required in section 584(d)(2)(C)(iii)(VI) of the FD&C Act, but also products that are unfit for distribution (see

proposed § 205.12(f)). Furthermore, any drug unfit for distribution should be segregated and returned or destroyed to prevent its distribution to the patient (see proposed § 205.12(f)(1)). These requirements will ensure that drugs, the distribution of which would violate the FD&C Act and which may not be fit for consumption by American consumers for a variety of reasons, are not distributed into the supply chain. FDA believes that these proposed standards align with current industry practices.

Similarly, to further ensure the safety and efficacy of drug products, FDA is proposing that 3PLs maintain written policies and procedures related to the storage, inventory, and disposition of both suspect and illegitimate products. In the case of a suspect product, the written policies and procedures must include the procedure for quarantine or destruction of the product if directed to do so by the product's manufacturer, wholesale distributor, dispenser, or an authorized government agency. In the instance of an illegitimate product, written policies and procedures must be in place to ensure that illegitimate product is appropriately dispositioned as directed by the respective manufacturer, wholesale distributor, dispenser, or authorized government agency. This may include segregation in a clearly defined, designated area from which the product may be dispositioned. FDA believes that these proposed standards align with current industry practices and will give 3PLs a clear roadmap for dealing with potentially difficult situations involving suspect and illegitimate product.

Finally, FDA views it as a best practice for a 3PL to establish written policies and procedures to ensure that it only engages in 3PL activities on behalf of authorized trading partners with respect to a product. DSCSA requires that all other entities that accept or transfer direct possession or ownership in the supply chain are only permitted to do business with other authorized trading partners (section 582 of the FD&C Act). FDA believes that, to further ensure supply chain security and integrity, it is important that 3PLs also only do business with other authorized trading partners. 3PLs that engage in transactions with non-authorized trading partners may expose the supply chain to potentially harmful or substandard product. FDA notes

that 3PLs are included in the wholesale distributor and third-party logistics provider reporting public database (available at https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm) which allows manufacturers, wholesale distributors, repackagers, and dispensers to determine if the 3PL is authorized. Similarly, 3PLs should include using the publicly available information regarding other trading partners in their written policies and procedures to ensure they are doing business with only authorized trading partners.

10. Recordkeeping and List of Trading Partners

The maintenance, availability, and accuracy of the records made available for inspection under section 584(d)(2)(D) of the FD&C Act is critical to demonstrate that 3PLs are acting in compliance with relevant laws and regulations and to ensure their records can be relied upon to identify any potential risk to the public health. As such, FDA is proposing to require that all records be securely stored, with procedures in place to restrict access and protect record integrity, and that any alterations made to records be signed and dated while preserving the original information contained in the record (see proposed § 205.13(a)). These records can be stored and maintained electronically. These records maintenance requirements will allow for greater confidence in both the information that is preserved at the facility and the information potentially disseminated to other trading partners.

FDA is proposing that all records must be retained for a minimum of 3 years, except for records related to suspect and illegitimate products, product quality complaints, and destroyed, returned, and recalled products, which each must be retained for a minimum of 6 years (see proposed § 205.13(b)). Such record retention is necessary not only to ensure 3PLs are complying with the FD&C Act, but also to ensure that there is consistency and continuity in the access to the information across the records required pursuant to sections 582, 583, and 584 of the FD&C Act. The DSCSA requires that, upon the licensing authority's request, 3PLs provide the licensing authority with a list of the trading partners (manufacturers, wholesale distributors, and

dispensers) for which the 3PL conducts 3PL activities (section 584(d)(2)(G) of the FD&C Act). This requirement would be codified in proposed § 205.14 and would also include repackagers for which the 3PL provides services when those repackagers are acting on behalf of a manufacturer, wholesale distributor, or dispenser of a product, as explained in the definition of *other logistics services* at § 205.3(i).

11. Annual and Other Reporting to FDA

Under DSCSA, 3PLs must report certain information to FDA to be considered an authorized trading partner (sections 581(2)(C) and 584(b) of the FD&C Act). The annual reporting requirements for 3PLs went into effect on November 27, 2014. Proposed § 205.15 clarifies the statutorily prescribed annual reporting requirements and proposes the collection of additional information to provide complete and useful information about 3PLs that can be used by FDA, States, and trading partners.

The DSCSA requires 3PLs to report to FDA for each facility: (1) the State by which the facility is licensed; (2) the facility's license number; (3) the facility's name and address; and (4) all trade names under which the facility conducts business (section 584(b) of the FD&C Act). If a facility conducts more than one type of activity, such as 3PL activities and wholesale distribution activities, the facility must be licensed as both a wholesale distributor and a 3PL and must report to FDA separately as a wholesale distributor and a 3PL (section 503(e)(2) of the FD&C Act).

FDA is proposing to require that 3PLs use an electronic system provided by FDA for reporting (see proposed § 205.15(a)). This electronic system will increase efficiency by providing uniformity in the content and format of reports, thereby making the information easier to process. FDA is proposing that the annual reporting schedule require all 3PLs to report each calendar year between January 1st and March 31st, although an entity may update information at any time (see proposed § 205.15(b)). For example, if a 3PL chooses to update a license on

December 15, 2019, that 3PL will still have to report during the January 1, 2020 through March 31, 2020 annual reporting period.

The specific information that 3PLs must electronically report to FDA is set forth in proposed § 205.15(c). The DSCSA requires that 3PLs report the name and address of each facility (section 584(b)(2) of the FD&C Act). In fulfilling this requirement, the 3PL must provide the address that is associated with the State or Federal license. Licensed entities are also required to report to FDA the State by which they are licensed and the license number (section 584(b)(1) of the FD&C Act). In addition, FDA is proposing to require that the reported company name be identical to the official company name appearing on the license (see proposed § 205.15(c)(2)). Maintaining an account in FDA's electronic system for each 3PL facility license during the reporting period is integral to FDA's ability to provide oversight, as each facility of a 3PL must be licensed in order for the 3PL to conduct 3PL activities.

In addition to the requirements specified in the statute, FDA is proposing to require an additional data element that FDA views as important to the Agency, the States, and trading partners. This additional information will inform other trading partners that the 3PL is in fact an authorized trading partner with whom they can do business. To this end, FDA is proposing to require that 3PLs provide the date each State license expires. This information is essential for determining that licensure status for each 3PL facility is current.

Also, in addition to the physical address, which is required to be reported by statute, FDA believes that it would be a best practice for 3PLs to submit a unique facility identifier (UFI) that corresponds with the facility name and facility address. The UFI for a 3PL facility is useful to FDA when identifying and confirming certain business information. To be most helpful to FDA and other trading partners, a 3PL should obtain a separate UFI for each *physical* address that the 3PL is reporting since each 3PL facility must meet the 3PL requirements, and licensure is facility specific. FDA also believes that it would be a best practice for 3PLs to submit the contact information of an individual who will interact with FDA, including that individual's name,

telephone number, and e-mail address. FDA recommends as a best practice that the 3PL designate a contact person who is familiar with the daily operations of the 3PL facility, such as the designated representative, to ensure efficient processing of inquiries and minimize the impact inquiries may have on the daily operations of the facility.

It is important for other trading partners and FDA to know whether a 3PL has had a license revoked or suspended or whether a 3PL has had any other significant disciplinary actions taken against them that limits the ability of a facility to conduct drug-related business. As such, 3PLs must report significant disciplinary actions to FDA. This will involve providing a DEA registration number or State controlled substance license number when there is a significant disciplinary action issued by the DEA or the State controlled substance licensing authority that would limit the ability of the 3PL facility to conduct 3PL activities related to the distribution of controlled drug substances that meet the definition of product, as defined at § 205.3(k). In such a situation, information about the DEA registration or State controlled substance license is important because the disciplinary action would likely be associated with that specific license or registration.

A *significant disciplinary action* is defined in the proposed regulation as an action that limits the ability of a facility to conduct 3PL activities related to the distribution of prescription drug products. FDA proposes that, within 30 calendar days after a significant disciplinary action is imposed or taken by a State or Federal government, 3PLs must report the type of disciplinary action, the date the action was taken, and the State where the disciplinary action occurred, as well as submit any documents associated with the disciplinary action, including a final ruling by the relevant State or Federal agency or board or a consent decree.

Finally, FDA is proposing to require a 3PL to report to FDA within 30 calendar days of ceasing warehousing or other logistics services that it is going out of business or voluntarily withdrawing a 3PL license from a State. FDA believes reporting this information is essential for

the information in the public database to be complete, accurate, and useful for FDA, the States, and trading partners.

To ensure efficient enforcement of FD&C Act requirements and to make public the voluntary information provided by each 3PL facility, FDA proposes adding 3PL licensure to the public database to make information about 3PLs available on FDA's website. Having the license status of 3PLs in one publicly available database will help FDA, trading partners, and other stakeholders determine whether 3PLs are properly licensed and authorized.

12. Inspection Provisions

Section 584(d)(2)(D) of the FD&C Act requires that the regulations provide for periodic inspections of 3PL facilities to ensure compliance with the national standards and directs FDA to determine the intervals at which periodic inspections of a 3PL will be conducted by the licensing authority to ensure a facility's compliance with the law and this regulation. To this end, FDA is proposing to require that a physical inspection of a 3PL facility be conducted prior to issuance of the initial license and routinely once every 3 years thereafter (see proposed § 205.16(a) and (b)). The regulation proposes allowing the licensing authority, or an AO, as determined by the licensing authority, to conduct physical inspections (see proposed § 205.16(a)). As used in part 205, subparts A and B, *licensing authority* means the State licensing authority or FDA. When developing the timeframes for inspections, FDA sought to balance the risk to the supply chain while considering FDA's and State agencies' resource constraints. FDA is proposing to require that the physical inspection of a 3PL facility warehouse space include the paper and electronically stored records detailing the processes related to all 3PL activities (see proposed § 205.16(c)). FDA has authority to require that an inspection of a 3PL warehouse include the 3PL's records, files, and processes related to product warehousing. Section 704(a)(1) of the FD&C Act (21 U.S.C. 374(a)(1)) states that "in the case of any . . . warehouse . . . in which prescription drugs . . . are held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities)." This authority directly applies to FDA's ability

to inspect a 3PL's facility warehouse space for relevant records and files to ensure compliance with the FD&C Act. FDA also proposes to require that 3PLs permit inspections at reasonable times and that the licensing authority conduct its inspection in a reasonable manner (see proposed § 205.16(c) and (d)).

D. Approved Organizations for 3PLs

1. Approval and Utilization of Outside Organizations in the Licensure Process

The DSCSA requires that regulations codified by FDA establish a process by which a third-party organization approved by FDA shall, upon a 3PL's request, "issue a license" to each 3PL facility that meets the requirements for licensure (section 584(d)(2)(A) of the FD&C Act). However, in situations where a State has not established a licensure program in accordance with the regulations, the DSCSA charges FDA with issuing 3PL licenses, provided the applicable requirements for licensure are met (section 584(a)(1)(B) of the FD&C Act). Accordingly, FDA interprets the language of 584(d)(2)(A) of the FD&C Act to mean that a third-party organization approved by FDA—an AO—will conduct a review of the 3PL's qualifications for licensure and issue a report to FDA regarding whether the 3PL "demonstrates that all applicable requirements for licensure . . . are met," which FDA can rely on when issuing a license per section 584(e) of the FD&C Act.

The DSCSA allows States and FDA to approve organizations for purposes of licensure review and periodic inspection. Proposed §§ 205.17, 205.18, and 205.19 contain the process that FDA will use to approve organizations and the qualifications to become an AO. FDA suggests that States that choose to rely on AOs for licensure reviews have in place the same or similar processes for approved organizations to conduct licensure reviews and for decisions affecting the approval status of those organizations.

The scope of work AOs would be tasked with performing and the standards an AO must meet to become approved are detailed in subpart B of proposed part 205. The proposed rules also

set forth the process by which FDA will approve organizations to review the qualifications of 3PL facilities for licensure, which we refer to as a "licensure review."

A licensure review consists of performing a review of all documents submitted to the licensing authority in support of an application for 3PL licensure and conducting an inspection of the facility as directed by the licensing authority. If a review of documentation supports licensure of the 3PL facility, the facility will then be inspected by an AO, as directed by FDA. FDA is proposing that the AO's licensure review be completed within 90 days upon receiving notice from the Agency to conduct the licensure review. FDA believes that this 90-day timeframe is sufficient for an AO to perform the work with which they are tasked while also ensuring that there are no undue delays in the licensure process. Upon completion of the licensure review, the AO would then provide FDA with a licensure review report within 7 days (see proposed § 205.17(b)), with a copy sent to the 3PL facility. As proposed, using the report submitted by the AO, FDA would make the final determination as to whether a 3PL facility should be issued a license. The process that AOs should follow when conducting routine inspections of 3PL facilities mirrors the process for licensure review and is detailed in proposed § 205.17(c).

It is important that FDA can verify an AO's continued compliance with the approval requirements. Therefore, to keep its approval, FDA is proposing to require that an AO maintain certain records for a period of at least 5 years and these records must be readily available to FDA upon request. Unless specified by statute, we believe it is reasonable for the required length of maintenance of records to align with the length of the entity's licensure term. In addition, to ensure public safety, FDA is proposing to require that AOs report potential violations at 3PL facilities to FDA within 24 hours of discovery (see proposed § 205.17(f)). The general qualifications for approval of AOs are set out in proposed § 205.18.

To become and remain approved, FDA is proposing to require that an organization, and those employed by the organization, abide by certain requirements that are intended to secure

against conflicts of interest, promote professional business practices, and protect non-public information (see proposed § 205.18(a)).

FDA is proposing to allow AOs to hire outside contractors to conduct licensure reviews or licensure review-related activities. Under FDA's proposed regulation, AOs who decide to use outside contractors must ensure that the contractors not only effectively carry out the licensure review or licensure review-related activities in a manner consistent with this proposed regulation to ensure public health, but the AO must also ensure that the contractors properly protect all non-public information.

For an AO to maintain approval, FDA proposes to require that the AO ensures contractors abide by all applicable confidentiality agreements, that the AOs have policies and procedures in place to ensure the contractors abide by these proposed standards, and that the contractors have the necessary training and expertise to carry out licensure reviews (see proposed § 205.18(b)(1)). Also, before a contractor hired by an AO may perform a licensure review of a 3PL facility, the 3PL must have entered into an agreement with the AO giving the AO permission to share with contractors the 3PL's confidential commercial information (see proposed § 205.18(b)(2)). If such consent is not provided by the 3PL facility, the AO must perform the licensure review itself. FDA believes that this approach is reasonable given that it is the AO's decision to work with contractors and, under this proposed regulation, the ultimate responsibility for the licensure review rests with the AO.

In addition, so FDA may keep track of which organization is responsible for each licensure review, FDA proposes that AOs must submit to FDA a list of the contractors used by the organization each year and the AO must certify that such contractors comply with the applicable requirements (see proposed § 205.18(b)(3)). Finally, to ensure that the standards set forth in this regulation are followed and that lines of responsibility are clear, FDA proposes to require that the AOs remain responsible for all the work performed by outside contractors (see proposed § 205.18(b)).

FDA proposes to prohibit contractors from subcontracting licensure review or licensure review-related activities (see proposed § 205.18(b)(1)(ii)). Limiting the ability of contractors to further delegate their responsibility ensures that FDA will have accurate information about who is conducting licensure reviews, that those responsible for the licensure reviews have the necessary qualifications, and that their conduct is governed by this proposed regulation.

The proposed process that FDA will use to approve organizations, including the application process, as well as the process for suspending or revoking an organization's approval, are set forth in proposed § 205.19. To ensure compliance with DSCSA, FDA is proposing that organizations seeking approval by FDA must first electronically submit to FDA an application demonstrating the organization's ability to assess compliance with all 3PL requirements detailed in proposed § 205.19 (see proposed § 205.19(a) and (b)). Organizations must also provide training that their employees must pass before they may conduct licensure reviews (see proposed § 205.19(c)). To verify information contained in the application and further ensure compliance with the proposed regulation, FDA proposes that, before an AO may conduct its first licensing review, it must be audited by FDA (see proposed § 205.19(d)). A new approval will be valid for 5 years (see proposed § 205.19 (e)).

If an organization's request for approval is denied, the organization may issue a request for reconsideration under 21 CFR 10.75 (see proposed § 205.19(f)). In addition, to ensure compliance and protect public health, FDA proposes that an AO may have its approval suspended if it does not maintain the standards outlined in this part (see proposed § 205.19(g)). A suspended AO must cease all 3PL licensure review including any pending inspections of 3PL facilities. A suspended AO must notify any 3PLs under a pending licensure review by the AO, of the AO's suspension within 7 calendar days (see proposed § 205.19(g)(5)). While most suspensions will happen only after notice and opportunity to request a hearing, under the proposed regulations, FDA reserves the ability to suspend approval prior to a hearing if there is a

reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans (see proposed § 205.19(h)).

Furthermore, FDA proposes that a suspended approval can be reinstated if the issue is resolved within 1 year from the date of suspension (see proposed § 205.19(i)), though it may be revoked if the organization fails to rectify the situation that resulted in the suspension (see proposed § 205.19(j)). FDA believes that 1 year provides the AO enough time to remedy most situations. An AO's approval may also be reinstated on a conditional basis. If the AO is conditionally reinstated, they will enter a three-year probationary period, during which if any material deficiencies arise, their license will be subject to immediate revocation (see proposed § 205.19(i)(2)).

FDA also proposes to permit an AO to voluntarily withdraw its approval, but it must inform FDA of any facilities with pending reviews (see proposed § 205.19(l)). To further ensure that pending licensure reviews are not overlooked, under FDA's proposed regulation, an AO whose approval has been suspended, revoked, or voluntarily withdrawn has the responsibility to report this information to those 3PL facilities with pending licensure reviews (see proposed § 205.19(m)); this will stop the clock on the 90-day licensure review while the 3PL applies for licensure review from another AO or FDA. Also, to ensure that the AOs continue to meet the standards put forth in this subpart, and part 205 generally, under the proposed regulations, an AO must inform FDA of any changes to information that was submitted as part of its application for approval (see proposed § 205.19(n)(1)). Since the approval of an organization is nontransferable, changes in ownership also require an AO to submit a new application to FDA (see proposed § 205.19(n)(2)). Finally, as an additional assurance that an AO continues to comply with the provisions of this part, FDA proposes to require that AO's remain subject to periodic audits by FDA (see proposed § 205.19(o)).

E. National Standards for Wholesale Distributors

1. Requirement That Wholesale Distributors Be Licensed

To implement section 503(e)(1) of the FD&C Act, FDA is proposing to codify at § 205.20(a) the requirement that a wholesale distributor be licensed by the State from which the drug is distributed, or by FDA if the State from which the drug is distributed has not established a licensure requirement in accordance with the standards proposed herein, as well as by the State into which the drug is distributed if that State requires such a license. This requirement is consistent with how States currently license wholesale distributors.

FDA anticipates that, for the purposes of annual reporting, a wholesale distributor who maintains multiple licenses to engage in wholesale distribution, will be able to report their required information aggregately for all their licenses (section 503(e)(2) of the FD&C Act). FDA believes this approach will increase efficiency for both wholesale distributors and the Agency, ensure that licenses for wholesale distribution facilities will be granted to qualified firms, and ensure records related to their facilities will be maintained in an organized fashion.

In addition, FDA proposes to set the licensure term for wholesale distributors at 2 years (see proposed § 205.20(b)). FDA considered current State requirements, as well as the potential impacts on State and Agency resources, to determine the term for licensure. Ultimately, the Agency believes that 2 years aligns with current practices, does not place an undue burden on State or FDA resources, and provides adequate protection to American consumers because it ensures that renewals will be based on current information and operations.

2. Surety Bonds

Wholesale distributors are required to obtain a surety bond to be licensed and engage in wholesale distribution (section 583(b)(3) of the FD&C Act). FDA is proposing to establish the terms of this requirement in proposed § 205.21. To receive or renew a license, a surety bond of $100,000, or $25,000 if applicable (for wholesale distributors with annual gross receipts of $10,000,000 or less), must be in place at the time the wholesale distributor's application for licensure or licensure renewal is submitted to the licensing authority (see proposed § 205.21(b)). The surety bond is intended to ensure compliance with DSCSA and that any administrative

penalties levied by the licensing authorities are paid. DSCSA also permits the furnishing of "other equivalent means of security acceptable to the State" in lieu of a bond (section 583(b)(3)(A)(i) of the FD&C Act). It would be up to the State licensing authority to determine what, if anything, would constitute an equivalent means of security to a surety bond. Where FDA is the licensor, the wholesale distributor would need to furnish a surety bond to satisfy the bond requirement as other equivalent means of security appear to be specifically reserved for the States.

While a bond is required before a wholesale distributor may acquire the necessary license, section 583(b)(3)(B) of the FD&C Act provides a set of circumstances under which the surety bond requirement will be waived. FDA is proposing to codify at § 205.21(b)(3) the DSCSA requirement that if a wholesale distributor can prove it has the necessary bond for the State where the facility is located (e.g., by providing a copy of the existing security bond agreement), the requirement for an additional surety bond for another State is waived. In this situation, the wholesale distributor does not have to acquire an additional bond to satisfy the non-resident licensure requirements of the State into which the wholesale distributor plans to distribute. However, it remains unclear if and how this waiver should apply when an equivalent means of security to the surety bond are used. FDA requests comment specifically related to the waiver to the surety bond requirement and whether that waiver should apply to scenarios where some other equivalent means of security is used in lieu of a surety bond.

The terms that a surety bond must include are outlined in proposed § 205.21(c). FDA proposes to require not only that the terms cover the liability requirements related to administrative penalties, but also that the bond remain in full force for 1 year after the license expires and that the surety company guarantee payment within 30 days of receiving notice from the licensing authority. FDA also proposes permitting licensing authorities to make claims against the surety bond for 1 year after the wholesale distributor's license expires or within 60 days after an administrative or legal proceeding has concluded, whichever is longer. These

timeframes seek to ensure that the rights of the different parties involved in a potential claim will be adequately protected. This is particularly important with respect to the waiver because it allows the affected States equal access to the surety bond and ensures consistent standards across States.

The implications of termination or lapse in coverage of a surety bond are detailed in proposed § 205.21(d). A wholesale distributor may cancel its surety bond, but FDA proposes to require that it give all impacted licensing authorities 30 days' prior notice before such cancellation take effect. Such notice is necessary because a wholesale distributor's license will be suspended upon the cancellation of the surety bond unless the wholesale distributor acquires a new bond before to the old bond is cancelled. FDA proposes that a license will be suspended if a licensing authority discovers a lapse in bond coverage.

FDA also proposes to require that the surety bond permit actions to be brought by either a State or Federal licensing authority (see proposed § 205.21(e)), provide the contact information for the surety company (see proposed § 205.21(f)), and name the specific parties to the surety bond (see proposed § 205.21(h)).

3. General Requirements for Licensure

This section includes the requirements for the application. FDA notes that the applicant would have to demonstrate compliance with the requirements as set forth in subpart C, including a satisfactory inspection, as described in proposed § 205.28, and criminal background checks for facility managers and designated representatives, as described in proposed § 205.25, to be granted a wholesale distributor license.

The general application requirements that must be met for a State or Federal licensing authority to issue a wholesale distributor license are set forth in proposed § 205.22. The requirements applicable to the individual who submits the licensure application are detailed in proposed § 205.22(a). FDA proposes to require that the applicant submit all required information

and pay a licensing fee in order to be considered for licensure. FDA believes these general requirements align with current industry practices.

FDA is proposing at § 205.22(b) to require that the applicant provide the surety bond or other equivalent means of security acceptable to the State, required by section 583(b)(3) of the FD&C Act and detailed in proposed § 205.21, as part of the wholesale distributor's application for a license.

The information that the licensing authority will require as part of a wholesale distributor's initial application for licensure and renewal applications is set forth in proposed § 205.22(c) and (d). This information is necessary for the licensing authority to assess whether the wholesale distributor is in good standing and has the infrastructure and capabilities to fulfill the duties and obligations of licensure. For example, FDA is proposing to require that a wholesale distributor inform FDA if it has received any citations for violating requirements for licensure or received any significant disciplinary actions within the past 7 years (see proposed § 205.22(c)(8)). FDA believes this information is necessary to ensure the wholesale distributor can demonstrate that it has not engaged in a pattern of violating the standards for licensure. The DSCSA defines prohibited persons, in part, as licensees who have "engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans" (section 583(d) of the FD&C Act). Therefore, this information is necessary to demonstrate that a wholesale distributor is not prohibited from receiving or maintaining licensure for wholesale distribution.

Finally, FDA proposes to require that a wholesale distributor's license be readily retrievable at the facility, and that the facility permit State or Federal inspectors, or others acting on behalf of the licensing authority, to inspect the license (see proposed § 205.22(e)).

4. The Federal Licensure Process

Section 503(e) of the FD&C Act, as amended by DSCSA, requires FDA to license wholesale distributors directly if the State in which it engages in wholesale distribution has not

established a licensing requirement (section 503(e)(1) of the FD&C Act). Proposed § 205.23 details the process that FDA will use when issuing licenses to wholesale distributors. While this section is only applicable to wholesale distributors obtaining a license from FDA, FDA suggests States implement similar procedures to ensure that all wholesale distributor licenses issued are consistent with the proposed regulation pursuant to section 503(e)(1)(B) of the FD&C Act. FDA plans to make information available to clarify who is the appropriate licensing authority in the wholesale distributor's State. FDA believes this streamlined process for application will allow for greater clarity and harmonization across the industry.

For wholesale distributor license applications submitted to FDA, FDA proposes that the wholesale distributor submit the application electronically, including the information outlined in proposed §§ 205.21 and 205.22, along with additional supporting documentation (see proposed § 205.23(a)(1)). The DSCSA authorizes FDA's use of third-party organizations—AOs—to conduct inspections of wholesale distributors required under section 583(c) of the FD&C Act. If FDA has approved one or more AOs to inspect wholesale distributors, the wholesale distributor should note the AO it prefers to conduct its inspection on the application submitted to FDA (see proposed § 205.23(a)(2)). If no AO has been approved, FDA will conduct the inspection (see proposed § 205.23(a)(3)). Furthermore, submission of the application to FDA will not be considered complete until FDA receives all pertinent information and fees (see proposed § 205.23(a)(5)).

While the DSCSA permits AOs to conduct inspections of wholesale distributors applying for licensure, the responsibility of determining whether a wholesale distributor meets all the applicable requirements set forth in this proposed regulation remains with FDA (see proposed § 205.23(b)). To avoid delays in the licensure process, FDA intends to work with wholesale distributors to correct minor errors made on the application (e.g., missing written policies and procedures) and communicate with the wholesale distributor about additional information the Agency may need to process and review the application (see proposed § 205.23(c)). If the

wholesale distributor meets the requirements outlined in this proposed part and none of the prohibited factors listed in proposed § 205.30(a)(1) are present, FDA will approve the application and send an approval letter and license certificate (see proposed § 205.23(d)).

FDA recognizes that a wholesale distributor may have concerns about what happens to the status of its license if disciplinary sanctions are taken against the approval status of the AO that conducted its inspection when applying for licensure or if the organization is otherwise no longer considered an approved AO. While FDA believes that a wholesale distributor should not be penalized for the actions of the AO, FDA must ensure that the AO's review and findings provide a reliable basis for licensing decisions. As such, FDA is proposing that, if the wholesale distributor is otherwise in good standing, a change in the approval status of the AO that conducted the inspection of the wholesale distributor will not automatically affect the licensure of a licensed wholesale distributor (see proposed § 205.23(e)). Rather, in the event that an AO has disciplinary sanctions taken against it, ends its business, or is otherwise no longer considered an approved AO, the license of any wholesale distributor reviewed by that AO will be subject to appropriate action in accordance with § 205.30 and other applicable statutes or regulations. FDA may verify the wholesale distributor's compliance status and review the facts in that situation to determine the potential effect, if any, on the licensure of wholesale distributors inspected by that AO.

5. Changes to Information, Ownership, or Location of Licensed Wholesale Distributors

FDA recognizes that information about a business can change over time. However, for the licensing authority to effectively carry out its responsibilities, license information must remain current and changes in information previously submitted must be reported to the licensing authority. Currently, the reporting requirements for these types of changes vary by State. FDA is proposing the establishment of specific timeframes for reporting changes (see proposed § 205.24) and believes that standardizing the timeframes will help make reporting business-related changes less burdensome for industry and licensing authorities. FDA is

proposing that the wholesale distributor submit changes to certain information, such as the information submitted with a surety bond or as part of an application for licensure, to the licensing authority within 30 calendar days of the date the change became effective (see proposed § 205.24(a)). Significant changes, such as changes in location or changes to the person engaged in wholesale distribution, require the added scrutiny that comes with an inspection or review of an application for a new license to ensure that the entity will be able to continue to meet the standards for licensure in its new location or under its new management. For this reason, FDA is proposing that changes in location or changes to the person engaged in wholesale distribution will require an inspection or new license (see proposed § 205.24(b) and (c)). FDA recognizes that the ownership of a facility from which a wholesale distributor leases the facility and conducts wholesale distribution may change without the wholesale distribution operation changing in any meaningful way. If that change does not impact the wholesale distribution operation, the wholesale distributor will not need to apply for a new license. As described in proposed § 205.24(b)(1), the date the change of location takes place is the date the new location begins receiving prescription drugs.

6. Prohibited Persons and Qualifications for Key Personnel

The FD&C Act, as amended by DSCSA, requires FDA to establish and implement standards for the qualifications of wholesale distributors' key personnel (section 583(b)(5) of the FD&C Act). As discussed above and proposed at § 205.3(g), FDA considers key personnel to include individuals with responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, facility manager or designated representative, or other individuals who are authorized to enter into areas where prescription drugs are held and are likely to handle those prescription drugs as a part of their responsibilities within the operation. FDA believes the qualifications for key personnel proposed in § 205.25 are necessary to ensure that all the individuals who are responsible for operating the

wholesale distributor's facility are appropriately qualified to carry out their duties and that the wholesale distributor meets the national standards.

Proposed § 205.25(a) lists conduct that prohibits a wholesale distributor from obtaining licensure. Proposed § 205.25(b) establishes the basic standards for key personnel working within a wholesale distribution facility. Key personnel must have the appropriate education, background, training, and experience necessary to carry out their assigned functions within the operation. No one within the facility should carry out the responsibilities of key personnel without the proper training and expertise.

As a part of FDA's responsibility to establish and implement standards for the qualifications of wholesale distributors' key personnel, FDA is proposing that wholesale distributors and their key personnel meet certain other qualifications. Licensure may be denied if a wholesale distributor or any of their key personnel do not meet the standards for qualification as outlined in proposed § 205.25(c).

Key personnel working for a wholesale distributor hold critical positions of trust for protecting the security of the prescription drug supply chain. FDA believes it would be a best practice for a firm to require that all employees not engage in the illegal use of controlled substances while serving in their capacity in the wholesale distribution operation and request that all employees so state.

FDA is proposing to require wholesale distributors to establish and implement written policies and procedures to ensure that their key personnel meet the qualifications contained in this proposed section (see proposed § 205.25(e)) and to maintain certain information about their key personnel that demonstrates they are qualified to carry out the duties assigned to them (see proposed § 205.25(b)), including having the proper education and training (see proposed § 205.25(e)(3)). Proposed § 205.25(f) also limits a facility manager or designated representative to hold that position at one facility at a time. This is to ensure that the facility manager or

designated representative is actively engaged in managing the daily operations of the facility and that they remain aware of any non-compliance issues that may arise.

The FD&C Act, as amended by DSCSA, specifically requires licensure standards to include mandatory background checks and fingerprinting of wholesale distributor facility managers and their designated representatives (section 583(b)(4) of the FD&C Act). Entrusting individuals with the responsibility of distributing prescription drugs prior to a criminal background check may jeopardize the integrity of the drug supply chain and leave the public exposed to unnecessary harm posed by the possible introduction of drugs that are unsafe. FDA is proposing to codify at § 205.25(g) the requirement for facility managers and their designated representatives to submit a full set of fingerprints to conduct local and national criminal background checks. The background check, when completed, must demonstrate that the facility manager or designated representative has no history of criminal convictions pursuant to proposed § 205.25(a).

FDA suggests, when a wholesale distributor staffs its operation, it is a best practice that the individuals who work within their operation and have access to prescription drugs not have a record of criminal activity involving violations of the FD&C Act or other laws involving prescription drugs. This best practice is recommended to help ensure security within a wholesale distributor.

When screening personnel who work in areas of a facility where prescription drugs are held, including the facility manager or designated representative, FDA recommends that a wholesale distributor consider whether such personnel have (1) engaged in a pattern of violating the requirements of section 583 of the FD&C Act that present a threat of serious adverse health consequences or death to humans; (2) been found to have committed or facilitated commission of any prohibited acts under the FD&C Act or violated or facilitated any violations of any of the regulations in this part or analogous provisions of the State licensing authority, as applicable; (3) been convicted of any violation Federal, State, or local laws relating to drug samples, wholesale

or retail drug distribution, distribution of controlled substances, or 3PL services; or (4) been convicted of any felony under Federal, State, or local laws involving or related to prescription drugs. FDA believes that wholesale distributors should consider an applicant's history of violations of the FD&C Act or other laws involving prescription drugs when making staffing decisions.

7. Wholesale Distributor Storage and Handling of Prescription Drugs, and Required Policies and Procedures

The DSCSA charges FDA with creating national standards for the storage and handling of prescription drugs by wholesale distributors, including facility requirements (section 583(b)(1) of the FD&C Act). To ensure confidence that the prescription drug delivered maintains its quality and integrity throughout the distribution process, FDA believes that wholesale distributors should establish and maintain quality systems that encompass the organizational structure, account for potential vulnerabilities or threats to the systems, and clearly articulate the procedures and processes for all wholesale distribution activity. A proper quality system should be fully documented, and the effectiveness of the system should be continually monitored to ensure the quality is maintained. This includes ensuring that facilities and equipment are properly maintained for their purposes of storing and distributing prescription drugs; that personnel are properly qualified, screened, and trained for their positions; and that documentation is comprehensive. Regular management review of all aspects of the quality systems in place is important for maintaining these high standards. FDA proposes § 205.26, which establishes basic requirements that will assist wholesale distributors in achieving these goals.

Although the FD&C Act permits an entity to be more than one type of trading partner so long as it complies with all the applicable requirements (section 582(a)(1) of the FD&C Act), FDA believes that the processes and functions of each type of entity need to be kept separate for the licensing authority to ensure the entity is complying with all the applicable requirements. Accordingly, FDA is proposing that any wholesale distributor's facility that is also licensed or

registered as another trading partner and operating from the same address must have separate systems and processes in place for their separate functions (see proposed § 205.26(a)).

FDA believes that proper storage and handling of prescription drugs inherently requires the establishment of standards that address physical requirements for the facility space in which drugs are stored and handled, along with standards that address the manner in which drugs are to be securely stored and handled within the facility of a wholesale distributor. In § 205.26(b), FDA proposes the following requirements with regard to standards placed on the wholesale distributor's facility. FDA believes these facility requirements will ensure that their establishments are appropriate for the distribution (including storage) of prescription drugs.

The facility must be of a suitable size, configuration, and design to ensure proper storage, maintenance, and cleanliness (see proposed § 205.26(b)(1)(ii) through (iv)). The facility must also be equipped with clearly defined areas that separate drugs that are unfit for distribution, from those that are saleable to avoid potential mistakes when distributing the prescription drugs (see proposed § 205.26(b)(1)(vi)).

The facility must be sufficiently secure to protect the prescription drugs in the supply chain from possible theft or diversion (see proposed § 205.26(b)(2)). Facilities must protect against unauthorized entry and ensure that the premises are well lit and not vulnerable to intrusion (see proposed § 205.26(b)(2)(i) through (iii)). Entry and access to areas where prescription drugs are held within the facility must be limited to those who have the appropriate experience and training needed to conduct wholesale distribution (see proposed § 205.26(b)(2)(iv)). These basic security requirements will help wholesale distributors protect and safeguard the prescription drugs maintained in their facility.

A wholesale distributor has the responsibility of ensuring that prescription drugs are stored under proper conditions to maintain the safety and effectiveness of the drugs it distributes. Accordingly, a wholesale distributor's facility must maintain appropriate equipment (e.g., refrigeration and air conditioning equipment) in good working order to ensure that prescription

drugs are properly stored in the facility (see proposed § 205.26(b)(3)). To this end, FDA is proposing to require that a wholesale distributor establish written procedures to ensure that its equipment is installed and maintained by qualified individuals (see proposed § 205.26(b)(3)(i)). Written policies and procedures include those that are stored and maintained electronically. Upon inspection, a wholesale distributor must demonstrate and verify that its equipment is in working order and has been periodically assessed in accordance with the wholesale distributor's written procedures to ensure the equipment's continued functionality (see proposed § 205.26(b)(3)(i)), which is critical in ensuring that those drugs retain their safety and effectiveness throughout the supply chain.

Additionally, a wholesale distributor must regularly conduct and document facility assessments to make sure that drugs are properly stored in accordance with their labeling (see proposed § 205.26(b)(4)).

FDA expects that, as a crucial part of the creation of a quality system, wholesale distributors will establish, maintain, and follow written policies and procedures regarding the safeguarding of the prescription drugs within their control. Proposed § 205.26(c) outlines several requirements for maintaining written policies and procedures to ensure that the requirements are carried out properly and consistently. Wholesale distributors are not limited to establishing written policies and procedures for the stated functions in proposed § 205.26(c), as a wholesale distributor may wish to establish written policies and procedures pertaining to other aspects of wholesale distribution and staffing of their facilities. The purpose of requiring written policies and procedures is to assist staff and management at a wholesale distribution facility to determine the processes required to ensure safe storage and distribution of prescription drugs.

Proposed § 205.26(c) includes the requirement that wholesale distributors establish and follow written policies and procedures to ensure that a wholesale distributor: (1) only does business with other authorized trading partners (see proposed § 205.26(c)(1)); (2) properly maintains equipment in good working order as outlined in proposed § 205.26(b)(3) (see proposed

§ 205.26(c)(2)); (3) transports prescription drugs in a manner designed to avoid breakage and exposure (see proposed § 205.26(c)(3)); (4) inspects shipping containers for suspect or illegitimate products, as well as other quality issues that may render the prescription drug unfit for distribution (see proposed § 205.26(c)(4)); (5) stores and handles the prescription drugs they warehouse and distribute in accordance with the prescription drug's labeling (see proposed § 205.26(c)(5)); (6) properly retains, returns, or destroys drugs removed from the supply chain depending on the proper disposition of the prescription drug (see proposed § 205.26(c)(6)); and (7) is prepared to protect against reasonably foreseeable crises that could affect security or operations at the facility (see proposed § 205.26(c)(7)).

8. Recordkeeping

Proper recordkeeping is essential to the timely identification, recording, and reporting of issues arising within the supply chain. Section 583(b)(2) of the FD&C Act requires FDA to create national standards for establishing and maintaining records pertaining to the distribution of prescription drugs. FDA is proposing in § 205.27(a) that these records include documentation pertaining to the security, storage, handling, inventory, shipping, sale, purchase, trade, delivery, and receipt of prescription drugs, as well as policies, procedures, instructions, contracts, data, inspection reports, and any other documentation related to compliance with this part, such as invoices, purchase orders, packing slips, and shipping records. These records could be stored and maintained electronically. These records maintenance requirements will allow for greater confidence in the information preserved at the facility and potentially disseminated to other trading partners.

The maintenance, availability, and accuracy of the records made available for inspection under section 583(b)(6) of the FD&C Act are critical to ensure that wholesale distributors are acting in compliance with this proposed regulation and that the records can be relied upon to identify any potential risk to the public health. As such, FDA is proposing to require that all records be securely stored, and that any alterations made to records be signed and dated, while

preserving the original information contained in the record (see proposed § 205.27(b)). This is intended to ensure that all records related to the distribution of prescription drugs provide transparency and accurately reflect the activities of the wholesale distributor. FDA also believes that reliability of the records is contingent on having processes and procedures in place that restrict access to and protect the integrity of the data. To this end, FDA is proposing to require in § 205.27(c) that wholesale distributors implement written policies and procedures to protect the integrity of their records.

Under proposed § 205.27(d), all records would be retained for a period of 3 years, except records related to suspect and illegitimate products, prescription drug quality complaints, and destroyed, returned, and recalled prescription drugs, which would need to be retained for a period of 6 years. Such record retention is necessary to ensure compliance and consistent enforcement of the various record keeping requirements of sections 582, 583, and 584 of the FD&C Act.

9. Inspections

Section 583(b)(6) of the FD&C Act directs FDA to establish national standards for a mandatory physical inspection of any facility used in wholesale distribution within a reasonable time frame from the initial application (section 583(b)(6) of the FD&C Act). FDA believes that it is imperative for the mandatory physical inspection to take place prior to issuing an initial license to a wholesale distributor to ensure that only those wholesale distributors who have the ability to properly store, handle, and distribute prescription drugs in accordance with the national standards are licensed. Accordingly, in proposed § 205.28(a), wholesale distributors are required to undergo a physical inspection before the licensing authority issues the initial license. As used in subpart C, *licensing authority* means the State licensing authority or FDA. To satisfy the inspection requirement, section 583(c) of the FD&C Act permits the licensing authority to conduct the inspection or accept an inspection by the State in which the facility is located or by a third-party accreditation or inspection service approved by the licensing authority in accordance

with these standards. FDA has codified this provision at proposed § 205.28(a)(1) and (2). Additionally, FDA believes that section 583(c) can be applied to State licensure of non-resident wholesale distributors to ship into a State and proposes that a State into which a drug is distributed may use the same methods to satisfy the inspection requirement for non-resident wholesale distributors (see proposed § 205.28(a)(1)(iii)). FDA believes that requiring a satisfactory inspection prior to licensure will ensure that only wholesale distributors with appropriate facilities and equipment for storing and distributing prescription drugs are granted a license to participate in the supply chain.

FDA is proposing to require that the physical inspection of wholesale distributor facilities include the facility itself, processes related to all wholesale distribution activities, and paper and electronically stored records; that wholesale distributors permit inspections at reasonable times; and that the licensing authority conduct its inspection in a reasonable manner (see proposed § 205.28(b) and (c)). FDA believes that authentication of records during an inspection is important to maintain confidence in documentation preserved by the wholesale distributor, which may contain information about nonsaleable prescription drugs or be disseminated to other trading partners.

FDA proposes that a wholesale distributor be required to make records available during inspections, including records that are held offsite in the normal course of business. The failure of a wholesale distributor to produce records in a timely manner during an inspection can significantly affect the licensing authority's ability to complete the inspection. Therefore, FDA is proposing that a wholesale distributor be required to provide offsite records within 2 business days of a request for such records by a State or Federal official, or sooner if necessitated by the duration of the inspection (see proposed § 205.28(b)). FDA also proposes the requirement that a wholesale distributor cooperate with the State or Federal licensing authority, or the AO conducting the inspection, at reasonable times, within reasonable limits, and in a reasonable manner to achieve the objective of the inspection (see proposed § 205.28(c)).

Finally, FDA believes routine inspections are an essential tool to ensure that wholesale distributors continue to comply with the national standards after obtaining their initial wholesale distributor license and move to renew that license. Accordingly, FDA is proposing to require that wholesale distributors undergo routine inspections at least once every 3 years (see proposed § 205.28(d)). In developing the inspection timeframes, FDA sought to balance the risk to the supply chain with FDA's and State licensing authorities' resource constraints. These routine inspections allow FDA or the licensing authority to ensure that wholesale distributors maintain the levels of quality storage and maintenance of prescription drugs at their facilities expected by FDA to safeguard the supply chain.

10. Annual and Other Reporting to FDA

Under DSCSA, wholesale distributors must report certain information to FDA as part of the requirement to be considered an authorized trading partner (sections 581(2)(B) and 503(e)(2)(A) of the FD&C Act). The annual reporting requirements for wholesale distributors went into effect on January 1, 2015, and FDA has published draft industry guidance that communicates draft Agency expectations for annual reporting while these regulations are being developed (79 FR 73083, December 9, 2014, and 82 FR 3004, January 10, 2017). Proposed § 205.29 clarifies the statutorily prescribed annual reporting requirements.

The DSCSA requires that any wholesale distributor who owns or operates an establishment that engages in wholesale distribution report to FDA on an annual basis: (1) the State in which the wholesale distributor is licensed; (2) the identification number of its wholesale distributor's license; (3) the name, address, and contact information for the wholesale distributor; (4) all trade names under which the licensed wholesale distributor conducts business; and (5) any significant disciplinary actions taken against the wholesale distributor (section 503(e)(2)(A) of the FD&C Act).

FDA is proposing to require that wholesale distributors use an electronic reporting system provided by FDA (see proposed § 205.29(a)). This electronic system will increase efficiency by

providing uniformity in report content and format, making the information easier to process for regularly updating the public database (section 503(e)(2)(B) of the FD&C Act). In addition, FDA believes having the license status of wholesale distributors in one publicly available database would be helpful for FDA, trading partners, and other stakeholders in determining whether wholesale distributors are authorized, as defined in section 581(2)(B) of the FD&C Act. Reporting information for each wholesale distributor in FDA's electronic system during the reporting period is integral to FDA's ability to provide oversight, as wholesale distributors are prohibited from distributing product without a license.

FDA proposes that the annual reporting schedule will require all wholesale distributors to report each calendar year between January 1st and March 31st, although an entity may update information at any time (see proposed § 205.29(b)). For example, if a wholesale distributor chooses to update a license on December 15, 2019, that wholesale distributor will still have to report during the January 1, 2020, through March 31, 2020, annual reporting period.

The specific information that wholesale distributors must electronically report to FDA is set forth in proposed § 205.29(c). The DSCSA requires licensed entities to report to FDA each State by which they are licensed and each license number (section 503(e)(2)(A)(i)(I) of the FD&C Act). FDA is proposing that the wholesale distributor also submit the expiration date of its State licenses (see proposed § 205.29(c)). The submission of the wholesale distributor's license expiration date is paramount to FDA's ability to establish and maintain a public database identifying each authorized wholesale distributor as required by section 503(e)(2)(B) of the FD&C Act. If a wholesale distributor's license expires, it is no longer an authorized trading partner, and FDA will remove it from the public database until the license is renewed or a new license issued. Similarly, FDA is proposing that a wholesale distributor be required to report to FDA within 30 calendar days that it has gone out of business or voluntarily withdrawn a wholesale distributor's license from a State (see proposed § 205.30(e)). Again, FDA believes that requiring a wholesale distributor to report this information about the status of its license is

essential for FDA to comply with the requirements under section 503(e)(2)(B) of the FD&C Act and to ensure that the database is accurate and helpful for the States and trading partners.

The DSCSA also requires that wholesale distributors report the name, address, and contact information for each facility at which, and all the trade names under which, the wholesale distributor conducts business (section 503(e)(2)(A)(i)(II) of the FD&C Act). In implementing this requirement, FDA is proposing to require the wholesale distributor to provide the company name that is identical to the official company name appearing on the license, along with the full business address that is associated with the State or Federal license (see proposed § 205.29(c)(2)).

Additionally, FDA is requesting that wholesale distributors submit a UFI that corresponds with the facility name and facility address. The UFI for a wholesale distributor's facility is useful to FDA in identifying and confirming certain business information. A wholesale distributor should obtain a separate UFI for each physical address it reports. FDA has published guidance on annual reporting that can assist wholesale distributors if they require additional information regarding the UFI reporting recommendation.

In addition, FDA believes the wholesale distributor's contact information should include someone familiar with the daily operations of the wholesale distributor's facility and who has the authority to act on inquiries to ensure efficient processing of inquiries and minimize the impact inquiries may have on the facility's daily operations. Therefore, wholesale distributors must submit the contact information of the facility manager or designated representative, including that individual's name, telephone number, and email address, with its annual reporting requirements pursuant to section 503(e)(2)(A)(i)(II) of the FD&C Act.

DSCSA requires a wholesale distributor to report to FDA any significant disciplinary action taken by a State or Federal government against the wholesale distributor (section 503(e)(2) of FD&C Act). A *significant disciplinary action* is defined in the proposed regulation, in relevant part, as any action by a State or Federal licensing authority that limits or prevents a

wholesale distributor from distributing or facilitating the distribution of prescription drugs (see proposed § 205.3(l)). FDA proposes that wholesale distributors report during the reporting period to FDA all significant disciplinary actions that occurred during the preceding 12-month period (see proposed § 205.29(d)(1)). After the reporting period, FDA proposes that within 30 calendar days after a significant disciplinary action is imposed or taken by a State or Federal government, wholesale distributors report the type of disciplinary action, the date the action was taken, and the State where the disciplinary action occurred, as well as submit any documents associated with the disciplinary action, including a final ruling by the relevant State or Federal agency or board or a consent decree (see proposed § 205.29(c)(4) and (d)). While wholesale distributors do not ordinarily have to report DEA registration numbers or State controlled substances licenses to FDA for annual reporting purposes, FDA suggests that such information be provided as part of its report under section 503(e)(2)(A)(ii) of the FD&C Act when there is a significant disciplinary action issued by the DEA or the State controlled substances licensing authority that would limit the ability of the wholesale distributor to distribute controlled drug substances. In such a situation, information about the DEA registration or State controlled substance license should be reported since the disciplinary action is reported under that specific license or registration.

11. Licensure Denial, Suspension, Reinstatement and Revocation--Notice and Opportunity To Request a Hearing

The standards for licensure denial are set forth in proposed § 205.30. Proposed § 205.30(a)(1) lists 10 circumstances under which a licensing authority will be required to deny a wholesale distributor's request for licensure or licensure renewal. FDA believes that these reasons requiring denial will ensure wholesale distributors focus on good storage practices outlined by FDA and are necessary to protect the integrity of the products in the pharmaceutical distribution supply chain. Wholesale distributors should seek to ensure that these reasons outlined in proposed § 205.30(a)(1) are addressed when the wholesale distributor files for licensure to avoid denial or delays of their application.

Proposed § 205.30(a)(2) through (5) details the process afforded to wholesale distributors whose applications for licensure have been denied. FDA is proposing to give applicants the opportunity to provide additional information for reconsideration of the denial. If the licensing authority denies a wholesale distributor's request for licensure after reconsideration, the wholesale distributor will receive a notice of opportunity to request for hearing under existing FDA hearing procedure. FDA requests comment regarding the reconsideration and appeal process outlined in this regulation for wholesale distributors whose applications for licensure have been denied.

The proposed standards for suspending a wholesale distributor's license are set forth in § 205.30(b) and (c). A suspended wholesale distributor must cease all receipt and distribution of prescription drugs until their license is re-instated. The proposed standards for suspension are based on the severity of risk posed to the public health. For example, under proposed § 205.30(b), a wholesale distributor's license may be suspended only after the wholesale distributor receives a notice of opportunity for hearing. If the licensing authority has a reasonable belief that the wholesale distributor is not in compliance with licensure requirements and such noncompliance threatens the quality of the product or threatens public safety, the licensing authority is required to notify the wholesale distributor in writing of the intent to suspend its license. A wholesale distributor will have 30 days upon the date of the notice of intent to suspend a license to provide additional information to the licensing authority so it may reconsider its decision to suspend the wholesale distributor license. If reconsideration is not sought, or if reconsideration is denied, the licensing authority will inform the wholesale distributor in writing of its formal intent to proceed with license suspension. The notice will contain a statement informing the wholesale distributor that it has an opportunity to request a hearing on the question of whether there are sufficient grounds for suspension. The wholesale distributor will have 10 days after the date of the notice to inform the licensing authority of its intent to request a hearing;

otherwise the opportunity for a hearing will be waived and the license suspended. FDA requests comment regarding this reconsideration and appeal process.

Proposed § 205.30(c) allows for suspension prior to notice and opportunity for a hearing and for suspension to be effective immediately if the wholesale distributor's noncompliance poses an imminent threat to public safety. For example, if a wholesale distributor is distributing illegitimate product, and once made aware, does not take corrective actions to protect the public from the threat of these products, its license could be suspended immediately. Another example would be a scenario where the conditions under which drugs are held cause the product to be illegitimate and the wholesale distributor refuses to correct the conditions or continues to ship these illegitimate products. Under the proposed regulation, if the licensing authority proceeds with suspension in such a situation, the licensing authority will inform the wholesale distributor in writing that its license is suspended. The notice will also contain a statement informing the wholesale distributor that it may request a hearing and that hearing, if granted, will be afforded within 10 days of the receipt of the wholesale distributor's request for hearing. The wholesale distributor has 10 days from the date on the notice of suspension to request a hearing; otherwise its opportunity for a hearing will be waived. FDA believes that this limits the amount of time a wholesale distributor's license would be suspended while providing a reasonable amount of time both for the wholesale distributor to review a notice of suspension and collect the necessary information to demonstrate that its license should not be suspended, and for FDA to consider the hearing request, and to schedule and prepare for a hearing, if the hearing request is granted. FDA believes immediate suspension of a wholesale distributor's license is crucial in cases where continued operation of the wholesale distributor presents an imminent threat to public safety and the pharmaceutical supply chain.

Under proposed § 205.30(d), a wholesale distributor's suspended license may be reinstated if the wholesale distributor can demonstrate to the licensing authority that it is in compliance with this proposed regulation.

Under the proposed rule the process outlined at § 10.75 is the default for appeals related to a denied application for a wholesale distributor license, and the hearing process outlined at 21 CFR part 16 is the default for appeals related to a suspended or revoked wholesale distributor license. However, the wholesale distributor may request any of the procedures contained in 21 CFR parts 10 through 16. FDA believes that this proposed approach is consistent with current practice and suggests that States develop comparable processes.

The standards for revoking a wholesale distributor license are set forth in proposed § 205.30(e). The licensing authority will revoke a license if it finds that a wholesale distributor whose license has been suspended is unable or refuses to comply with the licensing requirements. The requirements governing the revocation of a wholesale distributor license are set forth in proposed § 205.30(e)(2) through (4) and mirror the process outlined in § 205.30(b)(2) through (7), with one exception: when the licensing authority informs the wholesale distributor of its intent to revoke a license, the wholesale distributor is given no opportunity for reconsideration since it already had an opportunity to rectify deficiencies while its license was suspended.

In addition, where a wholesale distributor fails to timely renew its application, the license will be considered expired and the wholesale distributor will need to submit an application for new licensure if it seeks to resume wholesale distribution activities, because the licensing authority may be unable to confirm that the wholesale distributor continues to meet all necessary licensure requirements (see proposed § 205.30(f)). If a wholesale distributor's license expires, it must cease receipt and distribution of prescription drugs until their license has been re-instated.

FDA is also proposing that the licensing authority will terminate a wholesale distributor's license upon request from the wholesale distributor when the request includes a notice of the wholesale distributor's intent to discontinue its activities and a waiver of an opportunity for a hearing. The wholesale distributor will be required to apply for a new license should it decide to resume wholesale distribution activities (see proposed § 205.30(g)).

F. Approved Organizations for Wholesale Distributors

1. Approval of Outside Organizations and Utilization of Such Organizations in the Licensure Process

The FD&C Act, as amended by DSCSA, allows the Federal or State licensing authority to accept inspections of wholesale distributors conducted by third-party accreditation or inspection services they have approved to be part of the licensure process (section 583(c) of FD&C Act). Subpart D of the proposed rules defines the scope of work these approved organizations (AOs) would be tasked with performing, as well as the standards an AO must meet to become approved by FDA. Additionally, this subpart will explain the circumstances in which an inspection conducted by an AO may be used, what activities the AOs have the authority to conduct and are expected to conduct, and the qualifications that each third-party organization must possess to become approved by FDA. FDA suggests that States that choose to rely on AOs to conduct inspections have in place the same or similar qualifications and processes for approved organizations to conduct those inspections and for decisions affecting the approval status of those organizations.

FDA proposes that an AO must complete an inspection no more than 90 days after receiving notice from the licensing authority to conduct an inspection (see proposed § 205.31(b)). FDA believes this allows AOs sufficient time to perform the work with which they are tasked while also ensuring that the wholesale distributor's activities are not significantly delayed or otherwise impacted due to delays in the inspection process. Upon completion of the inspection, the AO would then provide FDA with a report based on the inspection within 7 days (see proposed § 205.31(b)(2) and (3)), with copy of the report to the wholesale distributor facility (see proposed § 205.31(b)(3)). Using the report submitted by the AO, FDA makes the final determination as to whether a wholesale distributor facility should be issued a license.

It is important that FDA be able to verify an AO's continued compliance with the requirements of the proposed regulation. Therefore, to become an AO and keep its approval,

FDA is proposing to require that an AO maintain certain records for a period of at least 5 years and make these records readily available to FDA upon request (see proposed § 205.31(c)). In addition, to ensure public safety, FDA is proposing to require that AOs report certain observations at wholesale distributor facilities to FDA immediately (see proposed § 205.31(c)(4)). The general qualifications for approval are set out in proposed § 205.32.

To become and remain approved, FDA is proposing to require that an organization, and those employed by the organization, abide by certain guidelines intended to secure against conflicts of interest, promote professional business practices, and protect non-public information (see proposed § 205.32(a)).

FDA is proposing to allow AOs to hire outside contractors to conduct inspections. Under FDA's proposed regulation, AOs who decide to use outside contractors must ensure that they effectively carry out the inspection in a manner consistent with this proposed regulation to protect public health, conform to conflict of interest provisions, and properly protect all non-public information (see proposed § 205.32(b)). For an AO to maintain approval, FDA proposes to require that the AO ensure contractors abide by all applicable confidentiality agreements, the AO has policies and procedures in place to ensure the contractors abide by these proposed standards, and the contractors have the necessary training and expertise to carry out inspections of wholesale distributor facilities (see proposed § 205.32(b)(1)).

Before a contractor hired by an AO may perform an inspection of a wholesale distributor, the wholesale distributor must have entered into an agreement with the AO giving the AO permission to share with contractors the wholesale distributor's confidential commercial information (see proposed § 205.32(b)(2)). If such consent is not provided by the wholesale distributor, the AO will perform the inspection itself, without the use of contractors. FDA believes that this approach is reasonable given that it is the AO's decision to work with contractors and, under this proposed regulation, the ultimate responsibility for the inspection and the protection of the wholesale distributor's information rests with the AO.

In addition, FDA proposes that AOs must submit to FDA a list of the contractors used by the organization and must certify that such contractors comply with the applicable regulations (see proposed § 205.32(b)(3)). Finally, to ensure that the standards set forth in this subpart are followed, FDA proposes to require that the AOs remain responsible for all the work performed by outside contractors (see proposed § 205.32(b)).

FDA proposes that to maintain their approved status, AOs must prohibit contractors from subcontracting their inspection duties (see proposed § 205.32(b)(1)(ii)). Limiting the ability of contactors to further delegate their responsibility ensures that FDA will have accurate information about who is conducting inspections, that those responsible for the inspections have the necessary qualifications, and that their conduct is governed by this proposed regulation.

The proposed process that FDA will use to approve organizations, including the application process, as well as the process for suspending or revoking an organization's approval, are set forth in proposed § 205.33. FDA is proposing that organizations seeking approval by FDA must electronically submit to FDA an application demonstrating the organization's ability to assess compliance with all wholesale distributor requirements detailed in proposed part 205 (see proposed § 205.33(a) and (b)), and employees must complete the necessary training as directed by FDA (see proposed § 205.33(c)). To verify information contained in the application and ensure compliance with the proposed regulation, FDA proposes that, before an AO may conduct its first inspection, a newly approved organization must be audited by FDA (see proposed § 205.33(d)). A new approval will be valid for 5 years (see proposed § 205.33(e)).

If an organization's request for approval is denied, the organization may submit a request for reconsideration under § 10.75 (see proposed § 205.33(f)). In addition, FDA proposes that an AO may have its approval suspended if it does not maintain the standards outlined in this section (see proposed § 205.33(g)). A suspended AO must cease all inspections of wholesale distributors. A suspended AO must notify any wholesale distributors with a pending inspection

to be performed by the AO of the AO's suspension within 7 calendar days (see proposed § 205.33(g)(5). While most suspensions will happen only after notice and opportunity to request a hearing, under the proposed regulations, FDA reserves the ability to suspend approval prior to a hearing if there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans (see proposed § 205.33(h)).

Furthermore, FDA proposes that a suspended approval can be reinstated if the issue is resolved within 1 year from the date of suspension (see proposed § 205.33(i)), though it may be revoked if the organization fails to rectify the situation that resulted in the suspension (see proposed § 205.33(j)). FDA believes that 1 year provides the AO enough time to remedy most situations. An AO's approval may also be reinstated on a conditional basis. If the AO is conditionally reinstated, they will enter a three-year probationary period, during which if any material deficiencies arise, their approval will be subject to immediate revocation (see proposed § 205.33(i)(2)).

FDA also proposes to permit an AO to voluntarily withdraw its approval or otherwise cease operations as an AO under this part, but it must inform FDA of any facilities with pending inspections (see proposed § 205.33(l)). To further ensure that pending inspections are not overlooked, under FDA's proposed regulation, an AO whose approval has been suspended or revoked has the responsibility to report this information to those wholesale distributors that have pending inspections (see proposed § 205.33(m)); this will stop the clock on the 90-day licensure review while the wholesale distributor applies for inspection from another AO or FDA. Also, to ensure wholesale distributors continue to comply with the provisions of this part, and to ensure that AOs remain able to assess compliance with the wholesale distributor requirements, an AO must inform FDA of any changes to information that was submitted as part of its application for approval (see proposed § 205.33(n)(1)). Since the approval of an organization is nontransferable, changes in ownership require an AO to submit a new application to FDA (see proposed §

205.33(n)(2)). Finally, as an additional assurance that an AO continues to comply with the provisions of this part, FDA proposes to require that AOs remain subject to periodic audits by FDA (see proposed § 205.33(o)).

VI. Proposed Effective/Compliance Dates

Section 584 of the FD&C Act states that the national licensing standards for 3PLs established by regulation take effect 1 year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act), and that national licensing standards for wholesale distributors established by regulation take effect 2 years after the date such final regulation is published (section 583(a) and (e)(3) of the FD&C Act). For several reasons, FDA does not intend to enforce the 3PL requirements until 2 years after the final regulation is published.

FDA recognizes that 1 year may be insufficient time for States to implement 3PL licensure programs, should they decide to implement such programs, and for 3PLs to apply for licensure under these programs. Setting up a state licensure program may require additional time. This is especially true in States that will require State legislative action to implement a licensure program, with some State legislatures only meeting biennially.

As the DSCSA states that the national standards for prescription drug wholesale distributors established by regulation pursuant to section 583 of the FD&C Act will take effect 2 years after the date such final regulation is published (section 583(a) and (e) of the FD&C Act), the national standards for licensing wholesale distributors in subpart C will be effective 2 years after the date the final rule is published.

Although the DSCSA states that the national licensing standards for 3PLs established by regulation pursuant to section 584 of the FD&C Act will take effect one year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act), as noted, FDA does not intend to enforce requirements with respect to the national standards for licensure of 3PLs until *2* years after the regulation is finalized, in order to provide States with the opportunity to establish or modify their licensure programs in accordance with the new standards and time for

3PLs to apply and obtain a new license. For 1 year after the effective date of the final regulation, FDA also does not intend to enforce the requirements of section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act with respect to a manufacturer, wholesale distributor, dispenser, or repackager who has as a trading partner a 3PL that is not licensed, unless the 3PL is not licensed because the Secretary or a state licensing body has made a finding that the 3PL does not utilize good handling and distribution practices and the Secretary has published notice thereof.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule could impose significant, although uncertain, new economic burdens on small entities, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross

Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

In this rulemaking, we propose new national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers as directed under the Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act. If finalized, the rule would also establish a Federal licensing system for wholesale drug distributors and third-party logistics providers to use in the absence of a state licensure program that is consistent with the proposed national standards.

This rulemaking is being published in conjunction with the proposed rule entitled "Certain Requirements Regarding Prescription Drug Marketing" (or part 203), published elsewhere in this issue of the *Federal Register*. We include the benefits and costs of part 203 in this economic analysis and, unless otherwise specified, references to the "proposed rule" in this analysis encompass both proposed rules.

We summarize the benefits and costs of the proposed rule in table 1. The standards for prescription drug wholesale distribution in the proposed rule would result in benefits to consumers and benefits to distributors from reducing the diversion of prescription drugs. Other monetized benefits include cost savings from reducing the frequency and quantity of licensure applications and cost savings from reducing state licensing standards in some states. We estimate that the annualized benefits over 10 years would range from $1.25 million to $31.50 million at a 7 percent discount rate, with a primary estimate of $10.66 million. We estimate that the annualized benefits would range from $1.26 million to $32.18 million at a 3 percent discount rate, with a primary estimate of $10.89 million.

We also expect that the proposed rule, if finalized, would impose costs on wholesale drug distributors, third-party logistics providers, states, approved organizations, and the Food and Drug Administration (FDA). Costs to wholesale drug distributors and third-party logistics providers include costs of learning about the rule, reporting to FDA, undergoing routine

inspections, writing and revising standard operating procedures, and conducting background checks. Wholesale-drug distributors would also incur costs to furnish surety bonds to their state licensing authority to obtain or renew their licenses.

Costs to states include the time spent reading and understanding the rule, passing or revising the laws and regulations governing their licensure programs, and inspecting WDD and 3PL facilities. Approved organizations would incur legal, application, and training costs, as well as costs to inspect WDD and 3PL facilities. FDA costs include the costs to establish and operate a reporting database and a licensure program for wholesale drug distributors and third-party logistics providers and the costs to establish and operate an approval program for approved organizations.

We estimate that the annualized costs over 10 years would range from $13.21 million to $20.63 million at a 7 percent discount rate, with a primary estimate of $16.92 million. We estimate that the annualized costs over 10 years at a 3 percent discount rate would range from $12.83 million to $20.10 million, with a primary estimate of $16.47 million.

Table 1.--Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($ millions/year)	$10.66	$1.25	$31.50	2020	7%	10 years	There is a high degree of uncertainty in the magnitude of benefits.
		$10.89	$1.26	$32.18	2020	3%	10 years	
	Qualitative							
Costs	Annualized Monetized ($ millions/year)	$16.92	$13.21	$20.63	2020	7%	10 years	
		$16.47	$12.83	$20.10	2020	3%	10 years	
	Qualitative							
Transfers	Federal Annualized Monetized ($ millions/year)	$0.12	$0.09	$0.14	2020	7%	10 years	
		$0.11	$0.08	$0.14	2020	3%	10 years	
		From: States			To: Firms			
	Other Annualized Monetized ($ millions/year)							
		From:			To:			
Effects	State, Local, or Tribal Government: Annualized net costs to states over 10 years ranging from $0.62 million to $1.44 million at a 7 percent discount and from $0.58 million to $1.38 million at a 3 percent discount rate.							

	Small Business: Quantified effects of more than 1 percent of average annual revenues for small 3PL firms. Unquantified effects are uncertain. Wages: No estimated effect. Growth: No estimated effect.	

We have developed a comprehensive Preliminary Economic Analysis of Impacts (PRIA) that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref 18) and at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

VIII. Analysis of Environmental Impacts

FDA has carefully considered the potential environmental effects of this action and has concluded, under 21 CFR 25.30(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). A description of these provisions is given in the Description section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requirements to Obtain a License to Distribute Drugs, Annual Reporting and Recordkeeping for Procedures, for Third-Party Logistics Providers and Prescription Drug Wholesale Distributors to Obtain a License to Distribute Drugs; 21 CFR part 205; OMB Control Number 0910-0251--Reinstatement

Description: The proposed rule would establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including process for the revocation, reissuance, and renewal of such licenses. Sections 584 and 583 of the FD&C Act (21 U.S.C. 360eee-3, 360eee-2)) as added by the DSCSA (Title II of Pub. L. 113-54) requires FDA to issue regulations on national standards for the licensing of 3PLs and wholesale distributors. Accordingly, FDA is proposing requirements for licensing of wholesale distributors and third-party logistics providers. The proposed rule outlines these requirements, including information collection provisions, that 3PLs and wholesale distributors must meet to obtain a license. The licensing authority is the State, from which the 3PLs distribute drug or the State from which wholesale distributors distribute drug. However, if a State does not establish the licensure programs for 3PLs or wholesale distributors consistent with these regulations, FDA will issue the licenses to 3PLs or wholesale distributors in that State. In addition, States may require that a 3PL or a wholesale distributor obtain a license to ship drugs into that State. The FD&C Act does not require that States issue these types of licenses. However, if a State chooses to implement such a licensure requirement, the State must ensure that it is consistent with these regulations, and any wholesale distributor or 3PL wishing to ship products into that State must have a license.

Proposed part 205, subpart A, would set forth the national licensing standards for State and Federal licenses issued to 3PLs pursuant to section 584 of the FD&C Act (21 U.S.C. 360eee-3). Proposed part 205, subpart C, would set forth the national licensing standards for State and Federal licenses issued to wholesale distributors pursuant to sections 503(e) and 583 of the FD&C Act (21 U.S.C. 353(e) and 21 U.S.C. 360eee-2)) and replaces the existing regulations in

proposed part 205 that outlined guidelines for State licensing of wholesale distributors that were developed under the Prescription Drug Marketing Act of 1987 (Pub. L. 100-293).

In addition, the FD&C Act, as amended by DSCSA, allows FDA to approve "third party accreditation" entities to evaluate the qualifications of 3PLs for licensure or inspect wholesale distributors facilities on behalf of FDA. These organizations are referred to in this proposed rule as approved organizations or "AOs." The application to become an AO is the same whether the AO will be evaluating the qualifications of 3PLs for licensure, inspecting wholesale distributors facilities, or both. Subparts B and D of the proposed rule outline the qualifications for AOs to perform licensure reviews/inspections for 3PL facilities and inspections of wholesale distributors respectively.

Description of Respondents: Respondents to the information collection are third-party logistics providers and wholesale distributors in any State and any entity engaging in wholesale distribution of prescription drugs in any State. We are proposing that these respondents submit applications for licensure and maintain records of procedures and documents pertaining to licensure review, inspections, policies, and training.

The DSCSA establishes 3PLs as members of the drug supply chain, which are distinct from wholesale drug distributors, and specifically precludes States from regulating 3PLs as wholesale distributors (section 585(b)(2) of the FD&C Act (21 U.S.C. 360eee-4(b)(2)). FDA is required by section 584 of the FD&C Act (21 U.S.C. 360eee-3) to establish national standards for the licensure of 3PLs and is proposing those standards in part 205, subpart A. When the proposed rule is finalized, we will require that each facility of an entity that meets the definition of a 3PL in section 581(22) of the FD&C Act (21 U.S.C. 360eee(22)) be licensed by the State or FDA in accordance with the standards articulated in proposed part 205, subpart A.

Proposed part 205, subpart C, of the proposed rule, §§ 205.20 through 205.30, establishes the national standards for the licensure of wholesale drug distributors. When the proposed rule is

finalized, we will require that each wholesale distributor be licensed by the State or FDA in accordance with the standards in proposed part 205, subpart C.

Proposed part 205, subpart B (§§205.17 through 205.19), and subpart D (§§205.31 through 205.33), of the proposed rule describe the content requirements, application process, and reporting schedules to become an approved organization to conduct licensure review/inspections for 3PL facilities or conduct inspections of wholesale distributors. Although the work differs among licensure review and inspection for 3PLs and wholesale distributors, FDA believes that the same entities will apply to conduct licensure reviews and inspection of both types of entities. In addition, the submission of an application to become an AO is the same in subparts B and D. Because of this, we are combining the discussions of AOs for 3PLs and wholesale distributors, and the resulting burden estimates.

The national licensure standards FDA is proposing are intended to help ensure that the supply chain remains secure and that those finished prescription drug products subject to the DSCSA moving through the supply chain are properly stored, handled, and transported. These measures are intended to help protect U.S. consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The required information collection to comply with the proposed rule is necessary for the States or FDA to assess the ability of 3PLs or wholesale distributors to properly maintain drug quality and security while the drug products are under their possession or control.

We estimate the burden of the information collection as follows:

Table 3.--Estimated Annual Reporting Burden[1]

Proposed 21 CFR Part 205 Section; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
SUBPART A (3PLs) §§ 205.5 and 205.6; application and process requirements	459	1	459	2	918
§ 205.7; changes to licensure	6	1	6	1	6
§ 205.8; expiry and renewal of licensure	149	1	149	1	149
§ 205.9; denials, suspensions, reinstatements, revocations	35	1	35	1	35

Proposed 21 CFR Part 205 Section; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§ 205.11; personnel list	459	1	459	.5	230
§ 205.15; annual reports	459	1	459	.25	115
SUBPART B (Approved Organizations for 3PLs) § 205.17; licensure review and inspection reports of 3PL facilities	6	15	90	5	450
§ 205.19; applications, denials, revocations, suspensions, renewals, reinstatements for AO status	3	1	3	2	6
SUBPART C (WDD Standards) §§ 205.22 and 205.23; application and process requirements for licensure	1,951	1	1,951	2	3,902
§ 205.24; changes to WDD information	39	1	39	1	39
§ 205.26; confirmation of theft or loss of Rx drug	25	1	25	.5	13
§§ 205.29 and 205.30; denials, suspensions, reinstatements, revisions, and terminations – requests for hearing	38	1	38	1	38
§ 205.29(a) – WDD annual reports	1,951	1	1,951	1	1,951
SUBPART D (Approved Organizations for WDDs) §§ 205.32 and 205.33; documentation of qualifications and disclosures to FDA	6	31	186	5	930
Total			5,890		

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

Table 4.--Estimated Annual Recordkeeping Burden[1]

Proposed 21 CFR part 205 section; IC Activity	No of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
SUBPART A (3PLs) 205.4; general requirements (retrievable records)	459	1	459	.5	230
205.12; written procedures	459	1	459	21	9,639
205.13; record and document maintenance	459	1	459	1	459
205.14; list of trading partners	459	1	459	2	918
SUBPART B (Approved Organizations for 3PLs) 205.17; licensure review and inspection records	6	15	90	2	180
205.19; written procedures, policies, training records	6	1	6	3	18
SUBPART C (WDD Standards)					
205.21; surety bond	1,951	1	1,951	1	1,951
205.25; personnel records	1,951	1	1,951	1	1,951
205.26; facility records	1,951	1	1,951	1	1,951

Proposed 21 CFR part 205 section; IC Activity	No of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
205.28; inspection records	1,951	1	1,951	1	1,951
SUBPART D (Approved Organizations for WDDs) 205.31; records demonstrating qualification status	6	1	6	1	6
TOTAL			9,742		19,254

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

Reporting Burden

Among the reporting requirements found in proposed part 205 are content and format provisions pertaining to issuance, changes, expiry, renewal, and annual reports for 3PLs, as well as WDDs, as reflected above in table 3. The proposed regulations also prescribe procedural steps and reporting schedules for submitting information regarding licensure, changes to licensure, reinstatement, and annual reporting, including requisite reporting timeframes. Consistent with our PRIA, we estimate that 459 3PL facilities and 1,951 WDDs will become subject to the reporting requirements described in proposed part 205, where we ascribe specific burden associated with the provisions found in table 3. Because we currently lack specific submission data regarding the proposed reporting requirements, we rely on our experience with similar information collection as the primary basis for our estimates. However, we invite specific comment from potential respondents regarding burden estimates we ascribe to the reporting elements found in the proposed regulations, along with a discussion of the basis for their computation.

Recordkeeping Burden

As set forth in the proposed regulations, 3PLs and WDDs must maintain records documenting procedures, management practice, policies, training, and personnel, among others. Under proposed § 205.4, all records are subject to FDA inspection and must be made available upon request in the format prescribed by the proposed regulations. Additional specific recordkeeping practice elements are also enumerated in the proposed regulations. Consistent with our PRIA, we estimate that 459 3PLs and 1,951 WDDs will become subject to these

requirements, if the proposed rule is finalized. These provisions are reflected above in table 4, along with an estimated number of annual records and recordkeeping hours we attribute to the corresponding activity. As with the proposed reporting requirements, we currently lack specific data regarding recordkeeping associated with the proposed regulations. We invite specific comment from potential respondents regarding burden estimates we ascribe to the recordkeeping activities, along with a discussion of the basis for their computation.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through reginfo.gov (see ADDRESSES). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the *Federal Register*.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132, "Federalism" (64 FR 43255, August 10, 1999). This Executive order sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, defined in section 1(a) of the order as including regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Section 4(a) of the Executive order requires agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." The DSCSA added to the FD&C Act an express

preemption provision under section 585, which addresses state licensure of WDDs and 3PLs in section 585(b)(1).

A. Scope of Preemption

FDA interprets section 585(b)(1) of the FD&C Act as preempting States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the standards and requirements applicable under sections 584 and amended 503(e) of the FD&C Act. In other words, States and local governments may not establish or continue licensure requirements for 3PLs or WDDs unless those State requirements are the same as Federal requirements; different requirements are preempted.

As noted above, a draft guidance issued in October 2014 (Ref. 4) proposed a different preemption interpretation under which States and localities could impose requirements on 3PL and WDD licensure that were different from Federal requirements so long as those requirements did not fall below the minimum Federal standards. Several stakeholders commented that the agency's interpretation of section 585(b)(1) was too narrow. Instead, they argued Congress intended to preempt all state licensure laws not identical to Federal licensure standards, i.e., that Congress wanted the Federal system to provide both a "floor" and a "ceiling" when it came to the issue of preemption.

FDA has reconsidered its earlier proposed interpretation and determined that its current interpretation – that the Federal requirements will establish both a "floor" and a "ceiling" – is more consistent with the language of the statute, Congressional purpose, and policy considerations. Section 585(b)(1) provides for the preemption of any state requirements that are, among other things, "inconsistent with" or "covered by" Federal requirements – which suggests both a floor and a ceiling. Furthermore, the fundamental purpose of the DSCSA provisions was to strengthen the security and integrity of the drug supply chain through uniform national requirements (Refs 2, 3, 18), including with respect to licensure (see e.g., section 583(b)). In contrast, under the interpretation proposed in our October 2014 draft guidance, 3PLs and WDDs

could be required to comply with a patchwork of State and local licensure requirements, which would undermine the goal of national uniformity and could create barriers to the statute's implementation and administrability. That approach would not create the intended uniformity in national policy because States and localities would not be preempted from establishing unique or disparate requirements.

Accordingly, FDA is withdrawing, as of the date of publication of this proposed rule, that portion of the October 2014 draft guidance addressing preemption with respect to WDD/3PL licensure.

B. Effective Date of Preemption

Section 585(b)(1) provides that it is effective "[b]eginning on the date of enactment of the Drug Supply Chain Security Act [November 27, 2013]." However, that provision applies only to state requirements that are inconsistent with the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act. Those national standards will be established by this regulation, once finalized and effective. Thus, by its very terms, section 585(b)(1) has no current application. Accordingly, State and local licensure requirements will be preempted only once this regulation, when finalized, takes effect; until such time, current State and local licensing of WDDs and 3PLs may continue.

We believe that this result is dictated by the terms of the statute. However, even if the statute were considered ambiguous, this interpretation is consistent with the statutory framework and purposes. Other provisions added by the DSCSA recognized state licensure of WDDs and 3PLs before the effective date of this regulation. For example, DSCSA requires both WDDs and 3PLs to report their state licensure, beginning January 1, 2015, for WDDs and November 27, 2014, for 3PLs (see sections 503(e)(2)(A) and section 584(b)). Because these reporting requirements apply during the period between DSCSA's enactment and the effective date of Federal licensing standards, they suggest that Congress intended to preserve the status quo in terms of permitting state licensure during this interim period. Indeed, if state licensing were

viewed as preempted during this interim period, there could be no valid state licensure for 3PLs and WDDs to report, rendering this reporting provision meaningless. In addition, section 582(a)(6) expressly recognizes state WDD licensure during the period between DSCSA's enactment and the effective date of Federal licensure regulations, and section 582(a)(7) similarly deems 3PLs to be "licensed" during this time, including by acknowledging and accommodating state licensure of 3PLs.

Further, the WDD licensure rules take effect two years after publication of the final rule, per section 583(e)(3), and the 3PL rules take effect one year after publication of the final rule, per section 584(d)(3)(C). Thus, despite the reference to DSCSA's enactment date in section 585(b)(1), the statute also expressly provides that the Federal licensure standards will not be effective until several years after DSCSA's enactment.

The interpretation is also supported by reading the provisions of a statute as an integrated whole, consistent with its fundamental purpose. As noted, the purpose is to strengthen the security and integrity of the drug supply chain through uniform national requirements, including with respect to licensure. This purpose would be frustrated if the statute were implemented in a manner that could lead to supply chain disruption, due to licensing uncertainties, while the national licensure standards are pending. Thus, Congress included in the DSCSA provisions which recognize state licensure of WDDs and 3PLs prior to the effective date of Federal licensing standards. If preemption under section 585(b)(1) were construed to preempt states from continuing to license WDDs and 3PLs even before Federal standards are in place, there could be confusion whether these supply chain entities have valid licensure, to the detriment of supply chain operations. Accordingly, we believe that read as a whole, the statute can be reasonably interpreted as providing for preemption to apply only upon the effective date of this regulation, once finalized.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the Federal Register, but websites are subject to change over time.

*1. 159 Cong. Rec. S8028 (2013) (Statement of Senator Barbara Mikulski); available at: https://www.congress.gov/113/crec/2013/11/14/CREC-2013-11-14-pt1-PgS8027-6.pdf.

*2. 159 Cong. Rec. H5964 (2013) (Statement of Representative James Matheson); available at: https://www.congress.gov/113/crec/2013/09/28/CREC-2013-09-28-pt1-PgH5946-2.pdf.

*3. 159 Cong. Rec. H5962 (2013) (Statement of Representative Robert Latta); available at: https://www.congress.gov/113/crec/2013/09/28/CREC-2013-09-28-pt1-PgH5946-2.pdf.

*4. FDA, Guidance for Industry: “Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party

Logistics Provider Licensing Standards and Requirements: Questions and Answers" October 2014, (available at https://www.fda.gov/media/89954/download), accessed December 14, 2021.

*5. Ducca, A., Healthcare Distribution Management Association, Public comment letter Document ID: FDA-2014-D-1411-0012, submitted on December 24, 2014, to Docket No. FDA-2014-D-1411 pertaining to the "Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability," October 8, 2014 (available at https://www.regulations.gov/document?D=FDA-2014-D-1411-0012), accessed December 14, 2021.

*6. Ventimiglia, V., Pharmaceutical Distribution Security Alliance, Public comment letter Document ID: FDA-2014-D-1411-0007, submitted on December 24, 2014, to Docket No. FDA-2014-D-1411 pertaining to the "Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability," October 8, 2014 (available at https://www.regulations.gov/document?D=FDA-2014-D-1411-0007), accessed December 14, 2021.

*7. Rouse O'Neill, L., Health Industry Distributors Alliance, Public comment letter Document ID: FDA-2014-D-1411-0013, submitted on December 24, 2014, to Docket No. FDA-2014-D-1411 pertaining to the "Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability," October 8, 2014 (available at https://www.regulations.gov/document?D=FDA-2014-D-1411-0013), accessed December 14, 2021.

8. Gallenagh, E.A, L.F. Hirsch, and K.L. Palmer, "Title II – Licensure of Wholesale Distributors and 3PLs," presented at Food and Drug Law Institute's Drug Quality Security Act

Conference, November 15, 2017 (available at https://www.fdli.org/wp-content/uploads/2017/11/DQSA-Hrisch-B.pdf), accessed December 14, 2021.

9. National Association of Boards of Pharmacy, "Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply," August 2013 (available at https://nabp.pharmacy/wp-content/uploads/2016/07/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-prescription-drug-supply.pdf), accessed December 14, 2021.

10. United States Department of Justice, "Three California Men and Minnesota Corporation Indicted in Nationwide Prescription Drug Diversion Scheme," May 2015 (available at https://www.justice.gov/opa/pr/three-california-men-and-minnesota-corporation-indicted-nationwide-prescription-drug), accessed December 14, 2021.

*11. United States Department of Justice, "Two Plead Guilty In Prescription Drug Diversion Scheme," May 2014 (available at https://www.justice.gov/usao-mdtn/pr/two-plead-guilty-prescription-drug-diversion-scheme), accessed December 14, 2021.

12. National Association of Boards of Pharmacy, "Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy" (available at https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/), accessed December 14, 2021.

13. Healthcare Distributors Alliance, "HDA Model Licensure Standards for Third-Party Logistics Providers for FDA Consideration," February 2015 (available at https://www.hda.org/~/media/pdfs/government-affairs/2015-02-10-traceability-resource-3pl-licensure-model.ashx), accessed December 14, 2021.

*14. World Health Organization, "Annex 5: WHO good distribution practices for pharmaceutical products," 2010 (available at https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf)), accessed December 14, 2021.

15. National Association of Boards of Pharmacy and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) (available at https://www.picscheme.org/), accessed December 14, 2021.

*16. U.S. Food and Drug Administration, "Prescription Drug Marketing Act, Report to Congress," June 2001 (available at https://wayback.archive-it.org/7993/20170405002846/https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/ucm203148.htm), accessed December 14, 2021.

17. National Association of Boards of Pharmacy, "Prescription Medication Distribution – The Five Percent Rule for Resale (Resolution 109-2-13)," June 2013 (available at https://nabp.pharmacy/news/news-releases/prescription-medication-distribution-the-five-percent-rule-for-resale-resolution-109-2-13/), accessed December 14, 2021.

18. FDA, "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers; Preliminary Regulatory Impacts Analysis," (available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm).

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Parts 12 and 16

Administrative practice and procedure.

21 CFR Part 205

Intergovernmental relations, Prescription drugs, Reporting and recordkeeping requirements, Security measures, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 10, 12, 16, and 205 be amended as follows:

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. In § 10.50, add paragraph (c)(21) to read as follows:

§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

* * * * *

(c) * * *

(21) Sections 503(e), 583, and 584 on denial, suspension, or revocation of third-party logistics provider licenses or wholesale distributor licenses.

PART 12--FORMAL EVIDENTIARY PUBLIC HEARING

3. The authority citation for part 12 continues to read as follows:

Authority: 21 U.S.C. 141-149, 321-393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b-263n, 264; 15 U.S.C. 1451-1461; 5 U.S.C. 551-558, 701-721; 28 U.S.C. 2112.

4. In § 12.21, revise paragraphs (a) introductory text and (a)(2) to read as follows:

§ 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 503(e); 505(d) or (e); 512(d), (e), (m)(3) or (4); 515(g)(1); 583; or 584 of the Federal Food, Drug, and Cosmetic Act, or section 351(a) of the Public Health Service Act, may be initiated--

* * * * *

(2) By a petition in the form specified elsewhere in this chapter, e.g., § 205.9 for licenses for third-party logistics providers, § 205.30 for licenses for wholesale distributors, § 314.50 for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products; or

* * * * *

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

5. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

6. In § 16.1:

a. Designate the 16 undesignated paragraphs immediately following paragraph (b)(1) as paragraphs (b)(1)(i) through (xvi).

b. In paragraph (b)(2):

i. Remove "§§" and "§" everywhere they appear and add "Sections" and "Section" in their places, respectively;

ii. Designate the first 14 undesignated paragraphs immediately following paragraph (b)(2) as paragraphs (b)(2)(i) through (xiv);

iii. Add paragraphs (b)(2)(xv) and (xvi); and

iv. Designate the last 23 undesignated paragraphs as paragraphs (b)(2)(xvii) through (xxxix).

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

(xv) Section 205.19, relating to revocation or suspension of approval for an approved organization to conduct licensure reviews for third-party logistics provider applicants.

(xvi) Section 205.33, relating to revocation or suspension of approval for an approved organization to conduct inspections of wholesale distributors.

* * * * *

7. Revise part 205 to read as follows:

PART 205--NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS AND PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS

Sec.

Authority: 21 U.S.C. 351, 352, 353, 360eee-2, 360eee-3, 360eee-4, 371, 374.

§ 205.1 Scope.

(a) This part applies to the licensure of third-party logistics providers (3PLs) in any State and to any entity engaging in wholesale distribution of prescription drugs in any State. The standards established under subpart A of this part will apply to all State and Federal licenses described under sections 503(e)(5) and 584 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(5) and 360eee-3). The standards established under subpart C of this part will apply

to all State and Federal licenses described under sections 503(e)(1) and 583 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(1) and 360eee-2).

(b) A facility or entity that conducts 3PL activities must obtain a 3PL license for each facility as described in this part and is not required to obtain a license as a wholesale distributor unless it is also conducting wholesale distribution activities, in which case, the entity or facility must obtain both a 3PL license as described in subpart A of this part and a wholesale distributor license as described in subpart C of this part. Unless otherwise noted, the term "3PL" or "third-party logistics provider" in this part applies to both the entity and the individual facilities requiring a license.

(c) Subpart B of this part applies to any third-party organization seeking to obtain or maintain approval by the Food and Drug Administration (FDA or the Agency) to evaluate the qualifications of 3PLs for licensure. Subpart D of this part applies to any third-party organization seeking to obtain or maintain approval by the Food and Drug Administration to conduct inspections of wholesale distributors.

§ 205.2 Purpose.

The purpose of this part is to establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including a process for the revocation, reissuance, and renewal of such licenses. This part also establishes the process and standards the Food and Drug Administration will use to approve third-party organizations to evaluate the qualifications of 3PLs for licensure and conduct inspections of wholesale distributor facilities.

§ 205.3 Definitions.

The definitions and interpretations of terms contained in section 581 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee) apply to those terms when used in this part. The following terms are also defined for purposes of this part:

(a) *3PL activities* means the provision or coordination of warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, while not taking ownership of the product, nor having the responsibility to direct the sale or disposition of the product.

(b) *Change of entity ownership* means:

(1) *Partnership.* In the case of a partnership, the removal, addition, or substitution of a partner.

(2) *Unincorporated sole proprietorship.* In the case of an unincorporated sole proprietorship, the transfer of title and property to another party.

(3) *Corporation.* In the case of a corporation, the merger of the licensed corporation into another corporation or the consolidation of two or more corporations, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the licensed corporation does not constitute change of entity ownership.

(4) *Limited liability company (LLC)*. In the case of an LLC, the merger of the licensed LLC into another LLC or the consolidation of two or more LLCs, resulting in the creation of a new LLC. Transfer of company stock or the merger of another LLC into the licensed LLC does not constitute change of ownership.

(c) *Co-licensed partner* means one of two or more entities that have entered a written agreement for the right to engage in the marketing of a prescription drug.

(d) *Designated representative* means an individual who is designated as the representative of the facility manager and is responsible for managing the daily operations of the wholesale distributor or 3PL facility.

(e) *Entity* or *entities* means a business organization, such as a corporation, company, association, firm, partnership, society, sole proprietorship, or joint stock company.

(f) *Facility* means an establishment, warehouse, structure, or structures under common ownership at one general, permanent, physical location used for distribution, including storage and handling, of prescription drugs.

(g) *Key personnel* means any individual who has responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, facility manager, or designated representative, or other individuals who are authorized to enter areas where prescription drugs are held and are likely to handle those prescription drugs as a part their responsibilities within the operation.

(h) *Minimal quantities* means the total annual dollar volume of prescription drugs sold by a retail pharmacy to licensed practitioners for office use does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription drug sales.

(i) *Other logistics services* include services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a trading partner (e.g., manufacturer, wholesale distributor, dispenser) but that do not take ownership of the product nor have the responsibility to direct a product's sale or disposition. "Other logistics services" also means services undertaken with respect to a product for a repackager acting on behalf of a manufacturer, wholesale distributor, or dispenser.

(j) *Other than a consumer* or *patient* means the person receiving the drug is not:

(1) The individual identified as the recipient of the prescription drug;

(2) A dispenser fulfilling a specific patient need as defined in section 581(19) of the Federal Food, Drug, and Cosmetic Act; or

(3) The clinical investigator, as defined in § 312.3(b) of this chapter.

(k) *Product* means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (e.g., capsules, tablets, lyophilized products before reconstitution).

(l) *Significant disciplinary action* means any action by a State or Federal licensing authority that limits or prevents a 3PL from conducting 3PL activities related to the distribution of prescription drugs, or limits or prevents a wholesale distributor from distributing, as that term is defined in section 581(5) of the Federal Food, Drug and Cosmetic Act, or facilitating the distribution of prescription drugs. This includes the revocation or suspension of a 3PL or wholesale distributor license, or of a registration with the Drug Enforcement Administration.

(m) *Unfit for distribution* means a prescription drug that has been identified as a drug whose sale would violate the Federal Food, Drug, and Cosmetic Act. This includes prescription drugs identified as suspect or illegitimate pursuant to section 582(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee-1(c)); adulterated pursuant to section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), including drugs rendered nonsaleable because conditions such as return, recall, damage, or expiry cast doubt on the drug's safety, identity, strength, quality, or purity; or misbranded pursuant to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

(n) *Wholesale distribution* means the distribution of a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) to a person other than a consumer or patient, or receipt of a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act by a person other than the consumer or patient, but does not include:

(1) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(2) The distribution of a drug or an offer to distribute a drug among hospitals or other health care entities that are under common control;

(3) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), except that, for purposes of this paragraph (n)(3), a drug

shortage not caused by a public health emergency will not constitute an emergency medical reason;

(4) The dispensing of a drug pursuant to a prescription executed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act;

(5) The distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use;

(6) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8) The distribution of a drug by the manufacturer of such drug;

(9) The receipt or transfer of a drug by an authorized 3PL, provided that such 3PL does not take ownership of the drug;

(10) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(11) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e) of the Federal Food, Drug, and Cosmetic Act;

(12) Saleable drug returns when conducted by a dispenser;

(13) The distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in paragraphs (n)(13)(i) through (iv) of this section as a *medical convenience kit*) if:

(i) The medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)(2));

(ii) The medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Controlled Substances Act;

(iii) In the case of a medical convenience kit that includes a product, the person that manufactures the kit:

(A) Purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(B) Did not alter the product's primary container or label as purchased from the manufacturer or wholesale distributor;

(iv) In the case of a medical convenience kit that includes a product, the product is:

(A) An intravenous solution intended for the replenishment of fluids and electrolytes;

(B) A product intended to maintain the equilibrium of water and minerals in the body;

(C) A product intended for irrigation or reconstitution;

(D) An anesthetic;

(E) An anticoagulant;

(F) A vasopressor; or

(G) A sympathomimetic;

(14) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body (such as dialysis solutions);

(16) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) The distribution of medical gas, as defined in section 575 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ddd);

(18) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager as described in section 581(16)(B) of the Federal Food, Drug, and Cosmetic Act and registered under section 510 of the Federal Food, Drug, and Cosmetic Act for the purpose of repackaging the drug for use by that hospital or other health care entity, and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

Subpart A--Third-Party Logistics Providers Licensure Standards

§ 205.4 Requirement that third-party logistics providers be licensed.

(a) No 3PL may conduct 3PL activities unless each facility of the 3PL is licensed:

(1) By the State from which the 3PL conducts 3PL activities; or

(2) If the State from which the 3PL conducts 3PL activities has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and

(3) If the product is distributed interstate, by the State into which the 3PL distributes the product if such licensure is required by that State, and the 3PL is not licensed by the Food and Drug Administration under § 205.6.

(b) Each facility owned, leased, or rented by a 3PL must have a separate license.

(c) Licenses are facility- and owner-specific and are not transferable.

(d) The 3PL must maintain its license at the licensed facility in a readily retrievable manner and must permit inspection of the license by any official, agent, or employee of the licensing authority or of any Federal, State, or local agency engaged in enforcement of laws relating to the distribution of prescription drugs.

§ 205.5 General application requirements for licensure.

(a) *Applicant requirements.* An individual who submits an application on behalf of a 3PL for a license issued pursuant to this subpart must:

(1) Be 18 years of age or older;

(2) Submit an affidavit that such individual's ownership or management of or employment by the 3PL would not preclude the 3PL from receiving or maintaining a license under § 205.11(f);

(3) Submit all application information required in the form required by the licensing authority; and

(4) Pay any licensing fees that are required by the licensing authority pursuant to section 584(c) of the Federal Food, Drug, and Cosmetic Act.

(b) *General requirements for licensure application.* The State or Federal licensing authority will require the following information from each 3PL facility as part of the initial application for the license described in § 205.4 and as part of any renewal of such license:

(1) The name and title of the individual who submits the application for licensure on behalf of the 3PL;

(2) The name of the 3PL as it should appear on the license, full business address of the facility, and telephone number;

(3) All trade or business names used by the 3PL, including prior trade or business names, within the past 7 years;

(4) Name, email address, and telephone number of the 3PL's facility manager or designated representative;

(5) The type of ownership or operation of the business entity, such as a partnership, corporation, limited liability company, or sole proprietorship;

(6) The name of any owners or operators of the 3PL, including:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the corporate names, the names of any subsidiaries and affiliates, the name and title of each corporate officer and director, and the State of incorporation; and

(iv) If a limited liability company, the name of the limited liability company, including any subsidiaries and affiliates, the name of each member, and the State in which the limited liability company was organized; and

(7) Whether the 3PL facility manager or designated representative has ever been convicted of a felony relating to prescription drug distribution, including a conviction under section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(i) or (k)) or 18 U.S.C. 1365, relating to product tampering, together with details concerning any such events.

(c) *General requirements for renewal applications*. On the renewal application provided by the State or Federal licensing authority, the 3PL must:

(1) Certify that the 3PL has continued to meet all the standards and complied with the requirements in this subpart since the previous license was issued; and

(2) Inform the applicable licensing authority of any changes to information previously submitted pursuant to paragraph (b) of this section or § 205.6(a)(2) for which a notification was not already submitted to the licensing authority under § 205.7.

§ 205.6 Federal licensure process.

(a) *Procedures for filing an FDA application for a 3PL license*. (1) Each 3PL facility must electronically submit an application to the Food and Drug Administration for a license to conduct 3PL activities in a State if the State does not have a 3PL licensure program consistent with the standards set forth in this section. The application must include the information specified in § 205.5, along with supporting documentation that demonstrates the applicant's storage practices are sufficient to ensure the continued safety, identity, strength, quality, and purity of the products in the facility.

(2) If one or more organizations have been approved by the Food and Drug Administration to conduct a review of a 3PL's qualifications for licensure pursuant to § 205.17, the 3PL will indicate in its application to the Food and Drug Administration which approved organization (AO) it prefers to conduct its licensure review. If there is no organization approved by the Food and Drug Administration to conduct licensure review, the Food and Drug Administration will conduct the review, as described in § 205.17(b). Licensure review must consist of:

(i) Review of all documents submitted in support of the application for 3PL licensure; and

(ii) Inspection of the facility, as directed by the licensing authority pursuant to § 205.16(a) or (b).

(3) The applicant, or the applicant's agent or other authorized official, must sign the application.

(4) An application for a 3PL license will not be considered as filed until the Food and Drug Administration has received all pertinent information and fees.

(b) *Determination that licensing requirements have been met*. The Food and Drug Administration, not an AO, will determine whether the 3PL meets all the applicable requirements set forth in this part.

(c) *Notification of easily correctable deficiencies*. The Food and Drug Administration will make every reasonable effort to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered, particularly deficiencies concerning storage, handling, distribution, or recordkeeping issues. The Food and Drug Administration will also promptly inform applicants of its need for more data or information or for changes in the application needed to facilitate the Agency's review.

(d) *Issuance of 3PL license by FDA*. Approval of a 3PL license application or issuance of a 3PL license constitutes a determination by the Food and Drug Administration that,

based upon the information provided and reviewed, the 3PL meets the applicable requirements to be licensed under section 584 of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration will approve an application and send the applicant an approval letter and license certificate if none of the reasons in § 205.9(a)(1) for refusing to approve the application applies. Applicable requirements for the maintenance of 3PL facilities to conduct 3PL activities will include but not be limited to the good storage practices set forth under § 205.10. A license is effective on the date of issuance of the license certificate.

(e) *Validity of 3PL license*. Licenses issued to 3PL facilities will remain valid until the date of expiration, unless suspended or revoked.

§ 205.7 Changes to information, location, or ownership of a licensed 3PL.

(a) Any change to any information required in this subpart, including changes to any information required pursuant to §§ 205.5, 205.6, 205.11, and 205.15, must be submitted electronically to the licensing authority within 30 calendar days after such change is effective, except where otherwise provided in this subpart.

(b) Any change in the location of a facility at which 3PL activities are conducted will require a new license and inspection of the new facility prior to its beginning operations.

(1) The application for a new license required by § 205.5 must be submitted no later than 90 calendar days prior to beginning operations at the new location.

(2) On the date the change of location takes place, the license for the original facility is void.

(c) Any change in the entity engaged in 3PL activities in a facility will require a new license prior to beginning operations.

(1) The application for a new license required by § 205.5 must be submitted no later than 30 calendar days prior to the change in ownership.

(2) A new inspection of the facility may also be required at the licensing authority's discretion.

(3) A 3PL can continue to operate under the original license for 30 calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner.

§ 205.8 Expiry and renewal.

Any license issued or renewed pursuant to § 205.5 or § 205.6 will expire 3 years after the date issued. A 3PL renewal application will not be accepted more than 90 calendar days before the date of expiration. A 3PL will not be penalized for administrative delay on the part of the licensing authority in issuing a new license. A license will be considered valid during the period of the administrative delay if the 3PL timely submitted the renewal application.

§ 205.9 Licensure denial, suspension, reinstatement, revocation, and voluntary termination: notice and opportunity to request a hearing.

(a) *Denial of application for licensure.* (1) The licensing authority will refuse to approve or renew a 3PL license application for any of the following reasons:

(i) The facilities and controls used for the receipt, security, storage, inventory, shipment, or distribution of the product are inadequate to facilitate safe operations pursuant to § 205.10(b).

(ii) The methods or procedures to be used in the receipt, security, storage, inventory, shipment, or distribution of the product do not comply with the requirements for good storage practices in § 205.10.

(iii) The personnel employed by the applicant do not meet the requirements necessary for good storage practices in § 205.11.

(iv) There is insufficient information in the written policies and procedures required in § 205.12 to determine whether the methods or procedures to be used in the receipt, security, storage, inventory, shipment, or distribution of the product comply with the requirements for good storage practices in § 205.10, or to determine whether the facilities and controls to be used

in the receipt, security, storage, inventory, shipment, or distribution of the product facilitate safe operations.

(v) The methods or procedures to be used in the receipt, storage, handling, or distribution of the product do not comply with the requirements for adequate recordkeeping in § 205.10 or § 205.13.

(vi) The application contains an untrue statement of material fact.

(vii) The applicant does not permit a properly authorized officer or employee of FDA, a State licensing authority, or an organization approved by the Food and Drug Administration pursuant to § 205.17 an adequate opportunity to inspect the facilities, controls, and any records relevant to the application.

(viii) For renewal applications, failure to report to the licensing authority any pertinent change of information required in § 205.5 or § 205.7.

(ix) For renewal applications, failure to comply with any of the requirements for annual reporting in § 205.15.

(2) If a 3PL's application fails to demonstrate that the 3PL meets the requirements for licensure set forth in this part, the licensing authority will provide written notice to the applicant that its license application may be denied, setting forth the grounds for the denial and an opportunity to demonstrate that the 3PL meets the requirements for licensure.

(3) The notice will inform the applicant of its right to provide additional information and request reconsideration of the denial by the licensing authority within 14 calendar days of the date of the licensing authority's written notice.

(4) If no reconsideration is sought or if, upon reconsideration, the licensing authority denies the applicant's request for licensure, the licensing authority will provide the applicant written notice of the denial and will provide the applicant notice of the opportunity to request a hearing.

(5) The applicant who wishes to request a hearing has 10 calendar days after the date of the notice of denial to submit a written notice of participation and request for a hearing. The applicant who fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(b) *Suspension of license after notice and opportunity to request a hearing*. (1) The licensing authority may move to suspend a license if the licensing authority has a reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart.

(2) The licensing authority will provide written notice of intent to suspend a 3PL license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate or achieve compliance. The notice will inform the applicant of its right to provide additional information, request reconsideration of the suspension by the licensing authority, and demonstrate or achieve compliance before suspension.

(3) Each 3PL license holder has 30 calendar days from the date of the notice of intent to suspend to present, in writing, comments and information bearing on the initial decision.

(4) If no comments or information are received within 30 calendar days or if, upon reconsideration, the licensing authority believes the 3PL license should still be suspended, the licensing authority will provide the 3PL a second written notice of the intent to suspend, informing the 3PL of the opportunity to request a hearing on the question of whether there are grounds for suspension.

(5) The written notice will contain a statement that the 3PL will be afforded an opportunity to request a hearing.

(6) The 3PL must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of notice of the intent to suspend. A 3PL that fails to

submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing and the license will be suspended.

(7) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(8) If a 3PL's license is suspended and the 3PL does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(c) *Immediate suspension of license*. (1) The licensing authority may suspend a license effective immediately if the licensing authority reasonably believes that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public health.

(2) The licensing authority will provide the 3PL with written notice of immediate suspension of its license setting forth the grounds for the immediate suspension pursuant to this part, including what information would be required to demonstrate compliance, and the opportunity to request a hearing within 10 calendar days of the 3PL's request for such hearing.

(3) The 3PL must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the written notice of immediate suspension. A 3PL that fails to submit a written notice of participation and request for hearing within 10 calendar days after the date of the written notice waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(5) If a 3PL's license is suspended and the 3PL does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(d) *Reinstatement of suspended licenses.* The licensing authority may reinstate a previously suspended license upon a 3PL's showing of compliance with requirements in this part and upon such inspection and examination as the licensing authority may require.

(e) *Revocation.* (1) If compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(2) The licensing authority will notify the 3PL of the intent to revoke the 3PL's license, setting forth the grounds for the revocation and offering an opportunity to request a hearing on the proposed revocation.

(3) The written notice will contain a statement that the 3PL may request a hearing.

(4) The 3PL must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. A 3PL that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(5) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(f) *Nonrenewal.* If a license is suspended and the 3PL does not submit a renewal application by the date of expiration of the suspended license, the license will be considered expired. A 3PL may not conduct 3PL activities with an expired license and must submit a new application for licensure if it wishes to conduct 3PL activities.

(g) *Voluntary termination of licensure upon request by the 3PL.* The licensing authority will terminate a 3PL facility's license upon the 3PL's request, which includes a notice of intent to discontinue its 3PL activities and waive opportunity for a hearing. A 3PL facility that voluntarily terminates licensure must obtain a new license before resuming 3PL activities.

(1) If a 3PL facility that has had its license revoked wishes to apply for a new license, that facility must submit a new license application, which may include an inspection if required by the licensing authority under § 205.16.

(2) [Reserved]

§ 205.10 Good storage practices for 3PL facilities.

(a) A facility owned, rented, or leased by a 3PL for the purpose of conducting 3PL activities must meet the storage practices for facilities required in paragraphs (b) through (d) of this section.

(b) A facility to which a 3PL license has been issued in the same name and at the same address as another trading partner, such as a wholesale distributor, must maintain separate systems and processes for products that are specific to the 3PL.

(c) A facility owned, leased, or rented by a 3PL in which 3PL activities are conducted must have suitable storage practices in place for such facility, as demonstrated by the following:

(1) *General requirements.* The facility is:

(i) Not a personal residence;

(ii) Of a suitable size, construction, and configuration to ensure proper storage and distribution of all products warehoused at the facility, including lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions where products are stored;

(iii) Of a suitable size, construction, and configuration to facilitate cleaning, maintenance, proper logistics, and distribution operations, and to provide protection from intrusion; and

(iv) Maintained in a clean and orderly condition, free from infestation of any kind.

(A) A cleaning program schedule must be maintained, documented, and followed.

(B) A pest control program, which is designed to ensure that the facility is free from infestation, must be in place, and pest control records must be kept.

(2) *Areas to handle separation of products that are unfit for distribution.* The facility has:

(i) Clearly defined, designated areas separate from saleable products to quarantine suspect product, illegitimate product, and other products that are unfit for distribution until dispositioned.

(ii) Clearly defined, designated areas to handle separation of products that are returned, recalled, or expired.

(iii) For returned or recalled products, clearly defined, designated areas separate from saleable products to handle returned or recalled product.

(iv) For expired products, clearly defined, designated areas separate from saleable products from which expired product may be returned to the manufacturer or repackager or destroyed.

(3) *Security of premises.* The facility is:

(i) Designed so that designated areas of the facility where products are held are accessible only to personnel, regardless of employee or contractor status, position title, or ownership interest, who possess appropriate and verifiable experience and training necessary to safely and lawfully engage in 3PL activities; and

(ii) Equipped with adequate security to protect from vulnerabilities and potential breaches. Adequate security must include precautions taken to ensure that:

(A) The facility is secure from unauthorized entry;

(B) Access from outside the premises is limited, well controlled, and documented;

(C) The outside perimeter of the premises is well lit;

(D) The facility is equipped with an alarm system to detect and notify appropriate personnel of entry after hours; and

(E) The facility is equipped with a security system that provides suitable protection against theft and diversion of products.

(4) *Facility assessments.* Facility assessments, including temperature mapping and other assessments designed to ensure products are properly stored in accordance with their labeling, must be regularly conducted and documented.

(5) *Equipment.* Equipment must be utilized and maintained in good repair and must be suitable for 3PL activities, as demonstrated by the following:

(i) The 3PL must be able to demonstrate that all equipment has been calibrated, as applicable, and validated at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following approved procedures;

(ii) The 3PL must use appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs to document proper storage of products; and

(iii) The monitoring equipment must alert appropriate personnel in a timely manner of any deviations from the intended storage conditions.

(d) In addition to the requirements set forth in this subpart, products must be handled and stored in accordance with all applicable Federal and State laws.

§ 205.11 Personnel requirements necessary for good storage practices.

(a) The 3PL must maintain a list of officers, directors, managers, and designated representatives; a description of their duties; and a summary of their qualifications. This list must be available for review by the State or Federal licensing authority.

(b) Qualifications for the 3PL's facility manager or designated representative of such facility manager must include that the individual:

(1) Has the education, background, training, and experience necessary to perform such individual's assigned functions;

(2) Serves as the facility manager or designated representative of such facility manager for only one facility at a time; and

(3) Is actively involved in and responsible for managing the daily operations of the 3PL facility.

(c) The 3PL must provide the facility manager or designated representative adequate authorities and resources to effectively manage the 3PL's daily operations in accordance with the standards in this part.

(d) The facility manager or designated representative is responsible for managing all the daily operations of the 3PL facility, including those duties delegated to other personnel.

(e) A 3PL is prohibited from obtaining or maintaining licensure if the 3PL employs a facility manager or designated representative who has been:

(1) Convicted of any felony violation of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act; or

(2) Convicted of any violation of 18 U.S.C. 1365, relating to product tampering.

(f) Licensure may also be denied when storage practices are not sufficient to maintain adequate security because a facility manager or designated representative of such facility manager has been:

(1) Found to have delayed or otherwise impeded an inspection by the Federal or State licensing authority or an approved third-party inspector, or if an inspector, after reasonable efforts, was unable to gain access to an establishment or a location to carry out the inspection required under § 205.16 as permitted by section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a));

(2) Found to have omitted material information or furnished false or fraudulent information in an application made in connection with the distribution of prescription drugs; or

(3) Subject to licensure suspension or revocation by Federal, State, or local government for any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances.

(g) Any facility manager or designated representative will be subject to criminal background checks. The results of the background checks must demonstrate no history of criminal convictions pursuant to paragraph (e) of this section.

§ 205.12 Required written policies and procedures.

(a) *General requirements for written policies and procedures.* Every 3PL must establish, maintain, and follow written policies and procedures as described in this section and relevant to the scope of their 3PL activities. The written policies and procedures must clearly delineate the responsibilities of the 3PL and any contractors used to fulfill any of the 3PL's duties. The written policies and procedures must also describe a system by which the 3PL will monitor all processes and, if deviations occur, document and investigate to determine the root cause of the deviation in a timely manner. Such written policies and procedures must be made available to the licensing authority upon request, and the licensing authority may copy records to ensure the 3PL is following written policies and procedures.

(1) Written policies and procedures must include, but are not limited to, the following:

(i) Documentation pertaining to receipt, security, storage, handling, inventory, shipment, and distribution of products, including written policies and procedures for identifying, recording, and reporting confirmed losses, thefts, diversions, and products unfit for distribution; and

(ii) Documentation pertaining to all policies, procedures, instructions, contracts, data, inspection reports, and any other documentation related to compliance with this part.

(b) *Personnel*. The 3PL must establish, maintain, and follow written policies and procedures that ensure the qualifications of personnel are met, maintained, and documented as required in § 205.11. These written policies and procedures must be available for review by the State or Federal licensing authority, as provided in § 205.13.

(c) *Written policies and procedures.* The 3PL must maintain written policies and procedures to address receipt, security, storage, inventory, shipment, and distribution of the product.

(1) *Receipt*. The 3PL must establish, maintain, and follow written policies and procedures providing for the inspection of all shipping containers in accordance with the following standards:

(i) *Incoming shipments*. Upon receipt, each shipping container must be visually examined for identity and for conditions that would suggest the product may be unfit for distribution.

(ii) *Outgoing shipments*. Each outgoing shipment must be properly inspected for identity of the product and to ensure that there is no shipment of product that is unfit for distribution.

(2) *Security*. The 3PL must establish, maintain, and follow written policies and procedures that provide for the secured storage of products and preserve the integrity of the 3PL's data and records.

(3) *Storage*. The 3PL must establish, maintain, and follow written policies and procedures that ensure products are stored at appropriate temperatures and under appropriate conditions, in accordance with the requirements in the products' labeling, to preserve their identity, strength, quality, and purity.

(4) *Inventory*. The 3PL must establish, maintain, and follow written policies and procedures related to inventory controls that:

(i) Ensure the facility's stock is inventoried regularly to protect against diversion and against distribution of product that may be unfit for distribution;

(ii) Contain procedures to identify, investigate, document, and correct stock errors, inaccuracies, and irregularities, including product theft, loss, or diversion;

(iii) Identify, record, and report confirmed product losses or theft immediately to the owner of the products and relevant authorities; and

(iv) Ensure that the 3PL can trace the receipt and outbound distribution of a product, as well as maintain supply and inventory records.

(5) *Shipment*. The 3PL must establish, maintain, and follow written policies and procedures providing for the transportation of products in accordance with the following standards:

(i) Products must be transported in a manner that will:

(A) Protect against breakage, contamination, adulteration, and theft;

(B) Prevent exposure to conditions that may compromise their quality and integrity; and

(C) Ensure that deviations from storage requirements during transport are promptly identified, investigated, documented, and reported to the trading partner from whom the product was received and to the manufacturer to determine if further commercial distribution is appropriate.

(ii) A 3PL that outsources transportation of products to a transportation provider, such as a common carrier, remains responsible for compliance with this part while the products are in transit to the intended trading partner. Arrangements for transportation by a transportation provider must be documented and carried out in accordance with the requirements in this section.

(6) *Distribution*. The 3PL must establish, maintain, and follow written policies and procedures related to the distribution of products that:

(i) Ensure products are distributed at appropriate temperatures and under appropriate conditions in accordance with the requirements in the products' labeling to preserve their identity, strength, quality, and purity; and

(ii) Protect against diversion and against distribution of products that may be unfit for distribution.

(d) *Recalled products*. The 3PL must establish, maintain, and follow written policies and procedures to support manufacturer recalls.

(e) *Preparing for foreseeable crises*. The 3PL must establish, maintain, and follow written policies and procedures to prepare for, protect against, and address any reasonably foreseeable crises that could affect security or operations (such as strike, fire, or flood).

(f) *Products that are unfit for distribution*. The 3PL must establish, maintain, and follow written policies and procedures for handling products that are adulterated, misbranded, or otherwise unfit for distribution, as well as returned products, that:

(1) Require such products to be physically segregated from other products and dispositioned as directed by the applicable manufacturer, wholesale distributor, dispenser, or an authorized government agency and in accordance with all applicable State and Federal laws;

(2) Identify a contact person responsible for communicating with the manufacturer, wholesale distributor, dispenser, or an authorized government agency regarding nonsaleable and returned products;

(3) Include procedures to prevent products unfit for distribution from entering the supply chain through the 3PL's disposition of nonsaleable products; and

(4) Require the 3PL to document the disposition of all nonsaleable and returned products, and maintain such records for inventory accountability.

(g) *Suspect product*. The 3PL must establish, maintain, and follow written policies and procedures to quarantine or destroy a suspect product if directed to do so by the product's manufacturer, wholesale distributor, dispenser, or an authorized government agency.

(h) *Illegitimate product*. The 3PL must establish, maintain, and follow written policies and procedures to store illegitimate product in a clearly defined, designated area from which the product may be dispositioned as directed by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

§ 205.13 Recordkeeping and document maintenance.

(a) *Maintenance, availability, and accuracy of records and written policies and procedures.* All required records and written policies and procedures outlined in § 205.12 must:

(1) Be readily retrievable and made available to licensing authorities upon request;

(2) Be securely stored from unauthorized access or modifications;

(3) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration; and

(4) Accurately reflect the name of the 3PL as it appears on the 3PL facility's license, which must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.15.

(b) *Record and document retention*. (1) Except for the records listed in paragraph (b)(2) of this section, all records and written policies and procedures required to be maintained by this part must be retained for a period of 3 years.

(2) Records of suspect and illegitimate products and destroyed, returned, and recalled products must be retained for a period of 6 years.

§ 205.14 3PLs must provide upon request a list of trading partners.

A list of all manufacturers, wholesale distributors, repackagers, and dispensers for which the 3PL conducts 3PL activities must be readily retrievable and made available to regulatory authorities upon request.

§ 205.15 Requirements for initial and annual reporting to the Food and Drug Administration.

(a) *Electronic reporting requirement.* The 3PL must report electronically to the Food and Drug Administration using a secure mechanism in a format the Food and Drug Administration can review, process, and archive. Information reported will be included in the Food and Drug Administration's public database for 3PLs to the extent allowable by law.

(b) *Reporting periods*--(1) *Initial reporting*. Any entity that owns or operates a facility that conducts 3PL activities must report to the Food and Drug Administration within 30 calendar days of obtaining an initial State or Federal 3PL license.

(2) *Annual reporting*. Any entity that owns or operates a facility that is licensed to engage in 3PL activities must report to the Food and Drug Administration each calendar year between January 1 and March 31.

(c) *Required information.* Information reported for each 3PL facility separately licensed by the licensing authority must include:

(1) A complete list of States by which the 3PL facility is licensed, including the corresponding identification number and the expiration date of each such license;

(2) Name of company as it appears on the license and full business address; and

(3) All trade names or business names under which the 3PL conducts business.

(d) *Timing for significant disciplinary action reporting*--(1) *Initial reporting*. The 3PL must report to the Food and Drug Administration any significant disciplinary actions that occurred in the previous 12 months.

(2) *Subsequent reporting*. The 3PL must, within 30 calendar days of a final action taken by a State or Federal licensing authority, report significant disciplinary actions to the Food and Drug Administration.

(e) *Reporting voluntary withdrawal of a State license*. The 3PL must report to the Food and Drug Administration that it has withdrawn its license in a State within 30 calendar days after such withdrawal, including the reasons for the voluntary withdrawal of licensure.

§ 205.16 Inspections.

(a) A physical inspection of a facility owned, rented, or leased by a 3PL for conducting 3PL activities must be conducted prior to issuance of the initial license by the licensing authority.

(1) Where the State is the licensing authority, the State may conduct the inspection or may accept an inspection by a third-party accreditation or inspection service approved by the State licensing authority. If the facility is out of state, the State may conduct the inspection or may accept an inspection by the State in which the facility is located.

(2) Where the Food and Drug Administration is the licensing authority, the Food and Drug Administration may conduct the inspection or may accept an inspection by an organization approved by the Food and Drug Administration under § 205.18.

(b) Routine inspections must be conducted thereafter once every 3 years by the licensing authority, a third-party approved organization or inspection service approved by the Food and Drug Administration under § 205.18, or the State licensing the 3PL.

(c) Records described in § 205.12(a)(1) that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or sooner if necessitated by the duration of the inspection.

(d) The 3PLs must permit the Federal or State licensing authority and third-party approved organizations or inspection services approved by the Food and Drug Administration or the State to enter and inspect their facilities and to audit their records and written operating procedures.

Subpart B--Approved Organizations for 3PLS

§ 205.17 Use of approved third-party organizations.

(a) A third-party organization that has been approved by the Food and Drug Administration pursuant to § 205.18 (or “approved organization” (AO)) may conduct licensure review of a 3PL’s qualifications for licensure and may conduct inspections of 3PLs at the periodic intervals specified in § 205.16, as directed by the Food and Drug Administration.

(b) If an organization has been approved by the Food and Drug Administration to conduct licensure review, the AO will:

(1) Conduct the licensure review, which consists of:

(i) Reviewing all documents submitted in support of the application for 3PL licensure; and

(ii) Inspecting the facility, as directed by the licensing authority;

(2) Complete the licensure review within a timeframe not to exceed 90 calendar days after receiving notice to conduct a licensure review from the Food and Drug Administration;

(3) Based on the licensure review, write a detailed document including any findings and observations in support of the AO's recommendation to the Food and Drug Administration to grant or deny licensure; and

(4) Send the original document to the Food and Drug Administration, with a copy to the 3PL, within 7 calendar days of completing the licensure review.

(c) When conducting routine inspections at periodic intervals, the AO will:

(1) Complete the inspection within a timeframe not to exceed 90 calendar days after receiving notice to conduct an inspection from the Food and Drug Administration;

(2) Based on the inspection, write a detailed document including any findings and observations in support of the AO's recommendation to the Food and Drug Administration regarding a 3PL's licensure; and

(3) Send the original document to the Food and Drug Administration, with a copy to the 3PL, within 7 calendar days of completing the inspection.

(d) To maintain approval, an organization approved by the Food and Drug Administration must:

(1) Maintain records that support the AO's initial and continuing qualifications for approval for a minimum of 5 years;

(2) Maintain the following records related to licensure reviews for a minimum of 5 years:

(i) Supporting documentation reviewed as part of a licensure review;

(ii) Licensure review and inspection reports;

(iii) Correspondence with the Food and Drug Administration and the 3PL associated with a licensure review; and

(iv) Information on the identity and qualifications of all AO personnel who contributed to the licensure review, including a certification that such personnel have complied with all applicable requirements set forth in subpart A of this part and are free of any conflicts of interest, as set forth at 5 CFR part 2635 and 18 U.S.C. 208.

(e) Records maintained by the AO must:

(1) Be readily retrievable and made available to Federal licensing authorities upon request;

(2) Be maintained and protected in accordance with all applicable laws, including those regarding protection of personal identifying information and confidential commercial information;

(3) Be secure from unauthorized access or modifications; and

(4) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(f) An AO must report to the Food and Drug Administration within 24 hours of discovering any evidence or observations of potential violations found at a 3PL facility during an inspection of the facility that could pose an imminent threat to the public health. Reports must be made in the manner prescribed by the Food and Drug Administration.

§ 205.18 General qualifications of approved organizations.

(a) To become and remain an AO, the organization and anyone employed by the organization, including contractors used by the organization:

(1) Must not be a current Federal or State government employee;

(2) Must not engage in prescription drug-related activities, excluding participation in the Agency's AO program and related activities, but including and not limited to manufacturing, wholesale distribution, repackaging, relabeling, dispensing, or 3PL activities;

(3) Must disclose to the Food and Drug Administration any participation or financial interest in entities that participate in the design, manufacture, promotion, or sale of articles or activities that are predominantly FDA-regulated or are expected to result in FDA-regulated articles;

(4) Must not be owned or controlled by, or have any organizational, material, or financial affiliation with, any of the entities engaged in manufacturing, wholesale distribution, repackaging, relabeling, dispensing, 3PL activities, or the design, manufacture, promotion, or sale of prescription drugs as defined in section 581(12) of the Federal Food, Drug, and Cosmetic Act;

(5) Must enter and abide by a written agreement with the applicant before data and information otherwise exempt from public disclosure may be disclosed to the AO or a contractor;

(6) Must operate in accordance with professional and ethical business practices and applicable legal requirements, which include, but are not limited to:

(i) Protecting against conflicts of interest as set forth in 5 CFR part 2635 and 18 U.S.C. 208;

(ii) Ensuring that the personnel employed or contracted by the AO who are working on licensure reviews have sufficient education, training, knowledge, and experience to conduct licensure reviews of 3PLs;

(iii) Treating received information, records, and reports that qualify as confidential commercial information as described at 5 U.S.C. 552(b)(4) according to applicable requirements for such information;

(iv) Maintaining appropriate security and protection, physical and electronic, of any information received in relation to licensure reviews to preserve confidentiality and ensure that the release of any information is limited to authorized disclosures to either the Food and Drug Administration or the 3PL facility;

(v) Reporting information to the Food and Drug Administration and entities for which licensure reviews were conducted that accurately reflects data reviewed, inspectional observations made, and other matters that relate to compliance with the Federal Food, Drug, and Cosmetic Act; and

(vi) Promptly responding to and attempting to resolve any complaints regarding activities for which it is approved by the Food and Drug Administration; and

(7) Must establish and maintain policies, procedures, and documentation to demonstrate that, at the time of application and throughout their tenure as an AO, the applicant has satisfied and can continue to satisfy the requirements to qualify as an AO capable of assessing compliance with all 3PL requirements. Such policies, procedures, and documentation must include, but are not limited to:

(i) AO program administration;

(ii) Disciplinary actions and corrective measures;

(iii) Recordkeeping and confidentiality;

(iv) Use of contractors; and

(v) Personnel qualifications and ongoing training.

(b) If an AO elects to use contractors for licensure reviews or licensure review-related activities, the AO remains responsible for the work of the contractors at all times.

(1) AOs that use contractors to conduct licensure reviews must abide by the confidentiality agreements between the Food and Drug Administration and the AO and have policies and procedures in place to ensure the contractor's continuing compliance with this part, as well as competence and qualifications to conduct licensure reviews. Such policies and procedures must ensure that contractors:

(i) Meet the qualifications set forth in paragraph (a) of this section;

(ii) Do not subcontract their licensure review duties, and that contractors are removed if such requirement is violated;

(iii) Abide by the policies and procedures of the AO, as set forth in § 205.19(b); and

(iv) Complete and pass the same training required by the AO, as set forth in § 205.19(c).

(2) If an AO elects to use contractors to conduct licensure reviews, the AO must receive and keep a record of written consent from the 3PL to share confidential commercial information with contractors by which a licensure review is being conducted.

(3) AOs that elect to use contractors must submit to the Food and Drug Administration a list of contractors used by the organization, accompanied by a statement from the organization certifying that such contractors meet the requirements of this subpart.

§ 205.19 Process and procedures for approval by the Food and Drug Administration.

(a) *Application.* An application to become an AO must be completed and submitted electronically to the Food and Drug Administration in a format the Food and Drug Administration can review, process, and archive.

(b) *Required application information.* Policies, procedures, and documentation as required by § 205.18(a)(7) must accompany the application.

(c) *Training*. Organizations must provide training as prescribed by the Food and Drug Administration, and any individual who conducts licensure reviews or supervises individuals who conduct licensure reviews is required to undergo and pass the prescribed training.

(1) If an individual does not pass training, that person must wait 30 days before retaking the training and may be required to show proof of additional education or experiential learning to demonstrate competence before retaking the training evaluation.

(2) To maintain approval, individuals employed by the AO and conducting licensure reviews or supervising those who conduct licensure reviews must undergo and pass annual training as prescribed by the Food and Drug Administration. Failure to complete and pass annual training may result in suspension of approval of the AO.

(3) The Food and Drug Administration may require additional training. If such additional training is required, AOs will be given a set time period during which training must be completed and passed to maintain approval.

(d) *Auditing*. Prior to conducting licensure reviews, an AO must undergo an onsite audit by the Food and Drug Administration. The Food and Drug Administration may also conduct random, periodic audits, as well as for-cause audits, of an AO, as set forth in paragraph (o) of this section.

(e) *Duration of approval and renewal process*. (1) The Food and Drug Administration approval to conduct licensure reviews is valid for a period of 5 years.

(2) AOs may submit a renewal application to the Food and Drug Administration 6 months prior to the expiration date, but no later than 3 months prior to the expiration date, to renew the approval.

(i) If a renewal application is submitted less than 3 months before the date of expiration, the AO's approval will expire if approval is not renewed prior to the date of expiration.

(ii) Upon expiration of the AO's approval, the AO must cease conducting any licensure review or inspection-related activities.

(f) *Denial of approval*. If an organization does not meet all of the Food and Drug Administration's standards detailed in §§ 205.17 and 205.18 for becoming an AO, the Food and Drug Administration will deny approval of the application in writing. Requests for review and

reconsideration of a denial of approval must be submitted to the Food and Drug Administration within 30 calendar days of the date of the Food and Drug Administration's decision to deny the application. If, upon reconsideration, the Food and Drug Administration denies the applicant's request for approval, the Food and Drug Administration will provide the applicant written notice of the denial and an opportunity to appeal pursuant to § 10.75 of this chapter.

(g) *Suspension of approval after notice and opportunity to request a hearing*. (1) The Food and Drug Administration may suspend approval of an organization after an opportunity to request a hearing when there is a reasonable probability that the organization's noncompliance will negatively impact public health.

(2) If an AO fails to maintain the Food and Drug Administration's standards pursuant to §§ 205.17 and 205.18, the Food and Drug Administration will give written notice of the intent to suspend the organization's approval, including the grounds for the suspension, and the AO will have 30 days to provide additional information to the Food and Drug Administration for reconsideration.

(3) If, upon reconsideration, the Food and Drug Administration still believes the AO's approval should be suspended, the Food and Drug Administration will issue the AO a written formal notice of intent to suspend, along with notice of the opportunity to request a hearing pursuant to part 16 of this chapter.

(4) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of intent to suspend to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days from the date of the notice waives the opportunity for a hearing.

(5) A suspended AO must notify any 3PLs under a pending licensure review by the AO of the AO's suspension within 7 calendar days.

(h) *Immediate suspension of approval*. (1) When there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or

death to humans, the Food and Drug Administration will suspend an AO's approval effective immediately.

(2) In such a situation, the Food and Drug Administration will provide the AO a written notice of immediate suspension, along with notice and opportunity to request a hearing pursuant to part 16 of this chapter within 14 calendar days of the AO's request for such hearing.

(3) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of suspension to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(i) *Reinstatement of approval*. (1) An organization's approval may be reinstated if the Food and Drug Administration determines that the suspended organization has rectified the issues leading to the suspension and can meet the standards set forth in this subpart. The organization must rectify the issues and come into compliance with the standards set forth in this subpart within 1 year from the date of suspension. If the issues have not been rectified within 1 year, or if the organization otherwise has failed to come into compliance with the standards set forth in this subpart within such time period, the Food and Drug Administration may revoke the AO's approval subject to the provisions of this part.

(2) An organization whose approval has been reinstated on a conditional basis will be subject to a 3-year probationary period, and if any material deficiencies arise during that period, the organization's approval will be revoked.

(j) *Revocation of approval*. (1) The Food and Drug Administration may revoke approval of an organization whose approval has been suspended pursuant to paragraphs (g) and (h) of this section:

(i) If an organization fails to demonstrate its intent to rectify the issues leading to the suspension within 6 months from the date of suspension; or

(ii) If the Food and Drug Administration determines that the organization failed to rectify the issues leading to the suspension to the Agency's satisfaction within 1 year of the date of suspension.

(2) The Food and Drug Administration will give written notice of the intent to revoke the organization's approval, including the grounds for the revocation, and an opportunity to request a hearing pursuant to part 16 of this chapter.

(3) The AO must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. An AO that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) An organization whose approval has been revoked that wishes to reapply to be an AO must submit a new application to the Food and Drug Administration.

(k) *Requests for reconsideration of Agency decision*. (1) The Food and Drug Administration will follow the process outlined at § 10.75 of this chapter to review matters relating to denial of approval, including review of the organization's application.

(2) The Food and Drug Administration will follow the process outlined at part 16 of this chapter to review matters relating to a suspension or revocation action, including review of the organization's application and administrative file.

(3) The Food and Drug Administration's decision after a request for reconsideration of denial, suspension, or revocation constitutes a final Agency action under 5 U.S.C. 702.

(l) *Voluntary withdrawal of approval*. (1) An organization wishing to voluntarily withdraw its approval, including but not limited to when an AO goes out of business, must notify the Food and Drug Administration in writing at least 6 months prior to the date the organization intends for the withdrawal to become effective.

(i) If an AO determines it will be withdrawing its approval with the Food and Drug Administration in less than 6 months, it must notify the Food and Drug Administration

immediately of its intent to withdraw, and such notification must inform the Food and Drug Administration of the date the organization will cease business operations.

(ii) [Reserved]

(2) No later than 7 calendar days after notifying FDA, the organization must notify any facilities with pending reviews that it intends to withdraw its approval with the Food and Drug Administration and must provide the date on which the withdrawal is effective.

(m) *AO-required notifications to 3PLs*. The AO must, within 7 calendar days of the date of suspension, revocation, or voluntary withdrawal of approval, notify those 3PL facilities that have pending licensure reviews of the AO's suspension or revocation. This notification must inform the 3PL facility that it must apply for licensure review with another AO, or the Food and Drug Administration if no other AO is available to conduct the licensure review.

(n) *Change of operation or ownership*. (1) The AO must report to the Food and Drug Administration within 30 calendar days any changes to the information submitted in the application for approval.

(2) Approval is not transferable.

(i) Changes in ownership of an AO require the organization to submit a new application to the Food and Drug Administration.

(ii) Such application must be submitted to the Food and Drug Administration no later than 30 calendar days prior to the date of the change of ownership.

(iii) No later than 30 calendar days before the date of the change of ownership, the AO must notify any 3PL facilities with pending applications of the pending change in ownership.

(iv) On the date the change of ownership takes place, the original approval is void.

(o) *Monitoring by the Food and Drug Administration*. (1) AOs are subject to audits by the Food and Drug Administration to ensure compliance with the Food and Drug Administration's requirements for approval.

(2) If an AO refuses to cooperate with the Food and Drug Administration's audit, the organization's approval may be suspended pursuant to paragraph (g)(1) of this section.

Subpart C--Wholesale Distributors Licensure Standards

§ 205.20 Requirement that prescription drug wholesale distributors be licensed.

(a) No wholesale distributor may engage in wholesale distribution of a prescription drug unless the person is licensed:

(1) By the State from which the drug is distributed; or

(2) If the State from which the drug is distributed has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and

(3) If the drug is distributed interstate, by the State into which the drug is distributed if such licensure is required by that State.

(b) Any license issued or renewed pursuant to this section will expire 2 years after the date on which the license was issued. A wholesale distributor may submit a renewal application up to 90 calendar days before the date of expiration. A license will be considered valid during any period of the administrative delay on the part of the licensing authority, if the wholesale distributor timely submitted the renewal application.

§ 205.21 Surety bond requirement.

(a) *Surety bond compliance.* No wholesale distributor will be licensed under this section unless the wholesale distributor has furnished a bond, or other equivalent means of security acceptable to the State if the State is the licensing authority, that complies with the requirements of this section.

(b) *Surety bond requirements*. (1) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government-owned and -operated wholesale distributor must submit to the licensing authority a surety bond from an authorized surety company of $100,000

or other equivalent means of security acceptable to the State. The term of the initial surety bond must be effective on the date that the application is submitted to the licensing authority.

(2) The licensing authority may accept a surety bond from an authorized surety company in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesale distributor are $10,000,000 or less.

(3) If a wholesale distributor can provide evidence that it possesses the required bond in the State where the wholesale distributor is located, the requirement for a bond in another State for a non-resident wholesale distributor license will be waived.

(c) *Terms of the surety bond*. (1) The terms of the bond submitted by a wholesale distributor must on its face reflect the requirements of this section, including meeting the requirements of liability coverage ($100,000 or $25,000, as applicable), as well as the responsibilities of the surety company and wholesale distributor as set forth in this section.

(2) The bond must be continuous and remain in full force and effect, running concurrently with the license period and for every succeeding licensing period for which the wholesale distributor may be licensed. The bond must remain in full force and effect until 1 year after the license expires, after which liability for license administrative fees ceases except as to any liability or indebtedness incurred or accrued before the termination date.

(3) The bond must guarantee that after receiving written notice from the licensing authority containing sufficient evidence to establish the surety's liability under the bond, the surety company will pay within 30 calendar days any administrative fines or penalties imposed by the licensing authority on the wholesale distributor holding the surety bond in that State. This includes any fees and costs incurred by the licensing authority regarding that license authorized by law and which the wholesale distributor fails to pay within 30 calendar days after the fine or costs become final. Any such claim may be made directly to the surety company and need not be preceded by the filing of any action in a proper court.

(4) The licensing authority may make a claim against the surety bond until 1 year after the date of expiration on the wholesale distributor's license or until 60 calendar days after any administrative or legal proceeding, which involved the wholesale distributor, is concluded, including any appeal, whichever occurs later.

(d) *Cancellation of a bond and lapse of surety bond coverage*. (1) A wholesale distributor may cancel its surety bond and must provide written notice 30 calendar days before the effective date of the cancellation to all applicable licensing authorities and the surety company.

(2) Cancellation of a surety bond is grounds for suspension of the wholesale distributor's license unless the wholesale distributor provides a new bond before the effective date of the bond's cancellation. If a new surety bond is provided before the effective date of the bond's cancellation, the liability of the surety company continues until the cancellation date. Otherwise, the liability of the surety company continues for 1 year after the date of cancellation, after which liability ceases except as to any liability or indebtedness incurred or accrued before the cancellation date.

(3) The wholesale distributor must immediately notify the licensing authority if there is a lapse in the wholesale distributor's surety coverage.

(4) If the licensing authority discovers a lapse in bond coverage that has not been previously disclosed by the wholesale distributor, the wholesale distributor's license will be suspended pursuant to § 205.30.

(e) *Actions under the surety bond.* The bond must provide that actions under the bond may be brought by a State or Federal licensing authority.

(f) *Required surety company information on the surety bond.* The bond must provide the surety company's name, street address or post office box number, city, State, and zip code.

(g) *Change of surety company*. A wholesale distributor that obtains a replacement surety bond from a different surety company to cover the remaining term of a previously obtained bond must submit the new surety bond to the licensing authority 30 calendar days prior to the

expiration of the previous surety bond. There must be no gap in the coverage of the surety bond periods.

(h) *Parties to the surety bond*. The surety bond must name the wholesale distributor as Principal, the licensing authority as obligee, and the surety company (and its heirs, executors, administrators, successors, and assignees, jointly and severally) as surety.

§ 205.22 General application requirements for licensure.

(a) *Applicant requirements.* An individual who submits an application on behalf of a wholesale distributor for a license issued pursuant to this subpart must:

(1) Be 18 years of age or older;

(2) Submit an affidavit that their ownership or management of or employment by the entity would not preclude the entity from receiving or maintaining a license under § 205.25(a);

(3) Submit all application information required in the form required by the licensing authority; and

(4) Pay any licensing fees that are required by the licensing authority pursuant to section 503(e)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) *Surety bond requirement.* The wholesale distributor must furnish a bond, or other equivalent means of security acceptable to the State, with the application for licensure in accordance with the surety bond requirements in § 205.21.

(c) *General requirements for licensure application.* The State or Federal licensing authority will require the following information from each wholesale distributor as part of the initial application for the license described in this section and as part of any renewal of such license:

(1) The name and title of the individual who submits the application for licensure on behalf of the wholesale distributor;

(2) The name of the wholesale distributor as it should appear on the license and the full business address and telephone number of the wholesale distributor;

(3) All trade or business names used by the wholesale distributor, including prior trade or business names, within the past 7 years;

(4) Name, email address, and telephone number of the designated representative or facility manager for the wholesale distributor;

(5) The type of ownership or operation of the business entity, such as a partnership, corporation, limited liability company, or sole proprietorship;

(6) The name of any owners or operators of the wholesale distributor, including:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the corporate names, the names of any subsidiaries and affiliates, the name and title of each corporate officer and director, and the State of incorporation; and

(iv) If a limited liability company, the name of the limited liability company, including any subsidiaries and affiliates, the name of each member, and the State in which the limited liability company was organized;

(7) Whether the wholesale distributor has ever been convicted of a felony relating to wholesale drug distribution, a felony conviction of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act, or a felony conviction of 18 U.S.C. 1365, relating to product tampering, together with details concerning any such events; and

(8) Whether the wholesale distributor has received any citations for violating requirements for licensure within the past 7 years or has received any significant disciplinary actions within the past 7 years that presented a threat of serious adverse health consequences or death to humans, together with details concerning any such events.

(d) *General requirements for licensure renewal*. To renew a license, the wholesale distributor must submit the following to the renewing licensing authority:

(1) Certification that the wholesale distributor has continued to meet all the standards and complied with the requirements in this subpart since the previous license was issued; and

(2) Information about any changes to information previously submitted under this section, or § 205.21, or § 205.23(c) for which a notification was not already submitted to the licensing authority under § 205.24.

(e) *License availability requirement.* The wholesale distributor must maintain its license in a readily retrievable manner and must permit inspection of the license by any official, agent, or employee of the licensing authority or of any Federal, State, or local agency engaged in enforcement of laws relating to the distribution of prescription drugs.

§ 205.23 Federal licensure process.

(a) *Procedures for filing an FDA application for a wholesale distributor license*. (1) All wholesale distributors must electronically submit an application to the Food and Drug Administration for a license to engage in wholesale distribution if the State does not have a licensing program for wholesale distributors consistent with the standards set forth in this section. The application must include the information in §§ 205.21 and 205.22, along with a surety bond and supporting documentation that demonstrates the applicant's ability to comply with requirements intended to ensure the continued safety, identity, strength, quality, and purity of the prescription drugs.

(2) If one or more organizations have been approved by the Food and Drug Administration under § 205.32 to conduct inspections of wholesale distributors, the wholesale distributor will indicate in its application to the Food and Drug Administration which AO it prefers to conduct its inspection.

(3) If there is no organization approved by the Food and Drug Administration to conduct inspections for wholesale distributors, the Food and Drug Administration will conduct the inspection, as described in § 205.28(b).

(4) The applicant, or the applicant's agent or other authorized official, must sign the application.

(5) An application for a wholesale distributor license will not be considered as filed until the Food and Drug Administration has received all required information and fees.

(b) *Determination that licensing requirements have been met*. The Food and Drug Administration, not an AO, will determine whether the wholesale distributor meets all the applicable requirements set forth in this part.

(c) *Notification of easily correctable deficiencies*. The Food and Drug Administration will make reasonable efforts to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered. The Food and Drug Administration will also promptly inform applicants if more data or information is needed to facilitate the Agency's review.

(d) *Issuance of wholesale distributor license by FDA*. Approval of a wholesale distributor license application or issuance of a wholesale distributor license constitutes a determination by the Food and Drug Administration that, based upon information received, the wholesale distributor meets the applicable requirements to be licensed under sections 503(e)(1) and 583 of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration will approve an application and send the applicant an approval letter and license certificate if none of the reasons in § 205.30(a)(1) for refusing to approve the application applies. Applicable requirements for wholesale distributors to engage in wholesale distribution must include but not be limited to the good storage practices set forth under § 205.26. A license is effective on the date of issuance of the license certificate.

(e) *Validity of a wholesale distributor license*. Licenses issued to a wholesale distributor will remain valid until the date of expiration, unless suspended or revoked.

§ 205.24 Changes to information, operation, location, or ownership of a wholesale distributor.

(a) Any change to any information required in this subpart, including changes to any information required pursuant to §§ 205.21, 205.22, and 205.25, must be submitted electronically to the licensing authority within 30 calendar days after such change is effective, except where otherwise provided in this subpart.

(b) Any change in the location of a wholesale distributor at which wholesale distribution occurs will require an inspection of the new facility prior to the wholesale distributor beginning operations at the new facility.

(1) On the date the change of location takes place, the wholesale distributor may not engage in wholesale distribution at the original facility.

(2) [Reserved]

(c) Any change in the person engaged in wholesale distribution will require a new license prior to beginning operations.

(1) The application for a new license required by § 205.23 must be submitted no later than 30 calendar days prior to the change in ownership.

(2) A new inspection of the wholesale distributor will be performed within a reasonable time.

(3) A wholesale distributor can continue to operate under the original license for 30 calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner.

§ 205.25 Prohibited persons and qualifications for key personnel.

(a) A wholesale distributor is prohibited from obtaining or maintaining licensure if the wholesale distributor has been:

(1) Convicted of any felony for violation of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act;

(2) Convicted of any felony violation of 18 U.S.C. 1365 relating to product tampering; or

(3) Cited on two or more occasions within the previous 7 years for violating one or more of the requirements of section 583 or section 503(e) of the Federal Food, Drug, and Cosmetic Act or State requirements for licensure in such a way that presents a threat of serious adverse health consequences or death to humans.

(b) All key personnel must have the education, background, training, and experience necessary to perform his or her assigned functions.

(c) Licensure may also be denied when an applicant wholesale distributor or any of their key personnel has been:

(1) Found to have delayed or otherwise impeded an inspection by the Federal or State licensing authority or an approved third-party inspector, or an inspector, after reasonable efforts, was unable to gain access to an establishment or a location to carry out the inspection required under § 205.28, as permitted by section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a));

(2) Found to have omitted material information or furnished false or fraudulent information in an application made about the distribution of prescription drugs; or

(3) Subject to licensure suspension or revocation by Federal, State, or local government for any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances.

(d) The wholesale distributor must maintain a list of officers, directors, facility managers, designated representatives, and other key personnel in charge of wholesale distribution, including storage and handling, and include a description of their duties and a summary of their qualifications. This list must be available for review by the State or Federal licensing authority.

(e) The wholesale distributor must establish and implement written policies and procedures designed to ensure that the qualifications of key personnel as required in this section are met, maintained, and documented. These written policies and procedures must be available

for review by the State or Federal licensing authority, as provided in § 205.27. These policies and procedures must identify the personnel at the wholesale distributor's facility who are responsible for the following actions:

(1) Implementing and maintaining all facility and personnel requirements;

(2) Ensuring that the facility complies with all licensure and reporting requirements; and

(3) Ensuring that key personnel receive initial and regular training to ensure competence relevant to their job functions.

(f) In addition to the qualifications for key personnel in paragraphs (a) through (e) of this section, a facility manager or designated representative must have the following qualifications to carry out those responsibilities:

(1) Serves as the facility manager or designated representative of such facility manager for only one facility at any one time;

(2) Is actively involved in and responsible for managing the daily operations of the wholesale distributor facility; and

(3) Remains responsible for all facility manager or designated representative duties that are delegated to other personnel at the facility.

(g) Any facility manager or designated representative, prior to their association, employment, or contracting with the wholesale distributor as a facility manager or designated representative, must submit a full set of fingerprints for purposes of conducting local and national criminal background checks. The results of the background checks must demonstrate no history of criminal convictions pursuant to paragraph (a) of this section.

§ 205.26 National standards for the storage and handling of prescription drugs for wholesale distribution.

Any facility owned, rented, or leased by a wholesale distributor for engaging in wholesale distribution must meet the facility requirements in paragraphs (a) and (b) of this

section, and the wholesale distributor must establish, maintain, and follow policies and procedures as set forth in paragraph (c) of this section.

(a) A wholesale distributor to which a license has been issued in the same name and at the same address as another authorized trading partner, such as a 3PL, must maintain separate systems and processes for the distribution of drugs that are specific to the wholesale distributor.

(b) The facility the wholesale distributor owns, leases, or rents for purposes of engaging in wholesale distribution must be suitable for the storage and handling of prescription drugs, as demonstrated by the following:

(1) *General requirements*. The facility is:

(i) Not a personal residence;

(ii) Of a suitable size, construction, and configuration designed to ensure proper distribution, including storage and handing, of all prescription drugs stored at or distributed from the facility;

(iii) Of a suitable size, construction, and configuration to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(iv) Maintained in a clean and orderly condition, free from infestation of any kind;

(v) Equipped with sufficient lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions for prescription drug storage; and

(vi) Equipped with clearly defined designated areas that separate saleable prescription drugs from prescription drugs that are unfit for distribution.

(2) *Security of premises*. The facility must be equipped with adequate security to prevent breaches. Adequate security includes ensuring that:

(i) The facility is secure from unauthorized entry;

(ii) Access from outside the premises is limited, well controlled, and documented;

(iii) The outside perimeter of the premises is well lit;

(iv) Entry into areas where prescription drugs are held is limited to key personnel who possess appropriate and verifiable experience and training necessary to safely and lawfully engage in the distribution of prescription drugs, as described in § 205.25, and to staff for purposes of maintenance and cleaning; and

(v) The facility is equipped with a security system that protects against theft and diversion of prescription drugs and accidental or unsanctioned modifications to data, including an alarm system to detect and notify appropriate personnel of any unauthorized entry.

(3) *Equipment*. The facility must have equipment that ensures prescription drugs are properly stored, including cold storage, refrigerators, temperature and humidity devices, and air handling units. All equipment utilized must be maintained in good repair and must be suitable for the distribution, including receipt, storing, and handling, warehousing, holding, displaying, or transporting of prescription drugs, as demonstrated by the following:

(i) All equipment must be installed, maintained, and repaired by qualified individuals following written procedures established by the wholesale distributor. The wholesale distributor must be able to demonstrate that all equipment has been calibrated, as applicable, and validated at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following the wholesale distributor's written procedures. Such actions must be documented;

(ii) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs must be used to document proper storage of prescription drugs; and

(iii) Monitoring equipment must immediately alert appropriate personnel of any deviations from the required storage conditions.

(4) *Facility assessments*. Facility assessments, including temperature mapping and other assessments designed to ensure prescription drugs are properly stored in accordance with their labeling, must be regularly conducted and documented.

(c) Every wholesale distributor must establish, maintain, and follow written policies and procedures for each of the requirements described in this section that are relevant to the scope of the wholesale distributor's activities involving prescription drugs at the facility. The written policies and procedures must describe a system by which the wholesale distributor will monitor all processes, and, if deviations occur, promptly document and investigate to determine the root cause of the deviation. If a wholesale distributor uses a contractor to carry out any of its duties, the wholesale distributor remains responsible for compliance with this subpart and must ensure that the contractor abides by the applicable written policies and procedures. The written policies and procedures must clearly describe the responsibilities of the wholesale distributor and any contractors used to fulfill the wholesale distributor's duties. Such arrangements must be documented and carried out in accordance with the requirements of this section.

(1) *Authorized trading partners*. The wholesale distributor must ensure that it conducts business only with other authorized trading partners as defined in section 581(2) and (23) of the Federal Food, Drug, and Cosmetic Act.

(2) *Facility and equipment maintenance management*. The wholesale distributor must ensure that the facility requirements in paragraph (b) of this section are met.

(3) *Transportation*. The wholesale distributor must ensure prescription drugs are transported in a manner that:

(i) Protects against breakage, contamination, adulteration, and theft;

(ii) Prevents exposure to conditions that may compromise prescription drug identity, strength, quality, or purity; and

(iii) Ensures that deviations from storage requirements during transport are identified, investigated, documented, corrected, and reported no later than 24 hours after discovery to the authorized trading partner from which the prescription drug was received, and to the manufacturer to determine if further commercial distribution is appropriate.

(4) *Examination of shipping containers*. The wholesale distributor must ensure that all shipping containers are examined in accordance with the following standards:

(i) *Incoming shipments*. Upon receipt, each shipping container must be visually examined for identity and to prevent the acceptance of prescription drugs that are unfit for distribution. This examination must be adequate to detect conditions that would suggest that the prescription drug may be unfit for distribution, such as alterations made or damage to the shipping container.

(ii) *Outgoing shipments*. Each outgoing shipment must be properly inspected for identity of the prescription drug to ensure that there is no shipment of a prescription drug that has been damaged in storage or held under improper conditions and to prevent the introduction or further shipment of any prescription drug that is unfit for distribution, including through the wholesale distributor's processing of returned or recalled drugs.

(5) *Storage and handling*. The wholesale distributor must ensure that prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with the drugs' labeling, except that if no storage requirements are established in the drug's labeling, the drug may be held at controlled room temperature to preserve the drug's identity, strength, quality, and purity.

(i) *Inventory management*. The wholesale distributor must:

(A) Ensure compliance with the requirements of section 582(c) of the Federal Food, Drug, and Cosmetic Act;

(B) Ensure that the facility's stock is inspected regularly to protect against drug diversion and distribution of prescription drugs that are unfit for distribution;

(C) Investigate, document, and correct any stock irregularities, including theft, loss, or diversion of prescription drugs, in accordance with section 582(c) of the Federal Food, Drug, and Cosmetic Act, as applicable;

(D) Ensure that any prescription drug that appears to be unfit for distribution is removed from saleable stock and handled appropriately according to the requirements in paragraphs (c)(5)(ii) through (iv) of this section;

(E) Immediately report any confirmed losses or theft of prescription drugs to the manufacturer of the drug and the Food and Drug Administration; and

(F) Ensure that records related to the actions required in paragraphs (c)(5)(i) through (iv) of this section are kept according to § 205.27.

(ii) *Handling of prescription drugs*. The wholesale distributor must ensure that only prescription drugs fit for distribution are further distributed or transferred.

(A) Any prescription drug that appears to be unfit for distribution must be stored in a secure area clearly defined for such use and physically segregated from saleable drugs, or electronically segregated, if appropriate, until the wholesale distributor determines by thorough examination that such drugs are fit for human use or nonsaleable.

(B) Any prescription drug found to be adulterated, misbranded, or otherwise unfit for distribution must be stored in a secure area clearly defined for such use and physically or electronically segregated from saleable drugs until they are returned to the supplier or destroyed in accordance with the standards in paragraph (c)(6) of this section.

(C) If a prescription drug is determined to be a suspect or illegitimate product, those suspect or illegitimate products must be handled according to the requirements of section 582(c)(4) of the Federal Food, Drug, and Cosmetic Act.

(iii) *Returned prescription drugs*. All returned prescription drugs must be stored in a secure area clearly defined for such use and physically segregated from saleable prescription drugs, until the wholesale distributor determines by thorough examination that such drugs are saleable or nonsaleable.

(A) *Saleable returns*. Prescription drugs may be returned to saleable stock only if the conditions under which the drug has been returned do not cast doubt on the drug's safety,

identity, strength, quality, or purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped.

(B) *Nonsaleable returns*. If the conditions under which the prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, drugs may be returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor, or may be destroyed in a timely manner and in accordance with paragraph (c)(6) of this section and all applicable Federal and State laws.

(iv) *Recalled drugs*. Recalled prescription drugs must be handled as instructed by the manufacturer in the recall notice, which may require that the recalled drugs be stored in a secure area clearly defined for such purpose and physically segregated from saleable drugs until they are returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor, or destroyed in accordance with the standards in paragraph (c)(6) of this section.

(6) *Disposition of drugs*. The wholesale distributor must establish, maintain, and follow written policies and procedures that ensure that prescription drugs removed from the pharmaceutical distribution supply chain because they are determined to be unfit for distribution are retained for further examination, returned to the manufacturer or repackager, returned to the wholesale distributor from which such drug was purchased, or returned to an individual acting on behalf of such an entity, including a returns processor, or destroyed in accordance with all applicable Federal and State laws and the following standards:

(i) *Quarantine and transfer for further examination*. The wholesale distributor must establish and maintain records for prescription drugs retained in quarantine and subsequently

transferred to a manufacturer or regulatory or law enforcement agency for further additional physical examination or laboratory analysis.

(ii) *Return the drugs*. The wholesale distributor must establish and maintain records for the return of prescription drugs to the manufacturer, repackager, or wholesale distributor from which the wholesale distributor acquired the drugs, including when returned using a returns processor or reverse logistics provider to return the drugs.

(iii) *Destroy*. When prescription drugs are authorized for destruction, the wholesale distributor must:

(A) Destroy all containers, labels, and packaging to ensure that such items cannot be used in counterfeiting activities;

(B) Ensure that the destruction of prescription drugs, containers, labels, and packaging are witnessed; and

(C) Establish and maintain records for destroyed drugs and the witnessing thereof.

(7) *Preparation for foreseeable crises*. The wholesale distributor must prepare for, protect against, and address any reasonably foreseeable crises that could affect security or operation of the facility such as strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

§ 205.27 Standards for the establishment and maintenance of records of the distribution of prescription drugs.

(a) *Required records.* Required records include, but are not limited to, the following:

(1) Documentation pertaining to distribution, including storage and handling, security, inventory, transport, and shipping of prescription drugs, including written policies and procedures for identifying, recording, and reporting confirmed losses, thefts, and diversions, and prescription drugs that are unfit for distribution;

(2) All policies, procedures, instructions, contracts, data, inspection reports, and any documentation related to compliance with this subpart; and

(3) Invoices, purchase orders, packing slips, shipping records, and any other records of the distribution of prescription drugs.

(b) *Maintenance, availability, and accuracy of records*. Records must:

(1) Accurately reflect the name of the wholesale distributor as it appears on the wholesale distributor license and must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.29;

(2) Be readily retrievable and made available to regulatory authorities upon request;

(3) Be securely stored and protected from unauthorized access or modifications; and

(4) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(c) *Written policies and procedures.* Written policies and procedures must be implemented by the wholesale distributor to protect the integrity of records.

(d) *Record retention*. (1) Except for the records listed in paragraph (d)(2) of this section, all records required to be maintained by this subpart must be retained for a period of 3 years.

(2) Records of investigation of suspect and illegitimate products and of destroyed, nonsaleable returned, and recalled prescription drugs must be retained for a period of 6 years.

§ 205.28 Inspections.

(a) A facility to be used in wholesale distribution must undergo a physical inspection prior to issuance of the initial license by the Federal or State licensing authority.

(1) Where the State is the licensing authority, such inspection may be conducted by:

(i) The State in which the facility to be licensed is located; or

(ii) A third-party accreditation or inspection service approved by the State licensing the wholesale distributor; or

(iii) If the facility is located out of State, the State issuing the license may conduct the inspection or may accept an inspection by the State in which the facility is located or by a third party, as described in paragraph (a)(1)(ii) of this section.

(2) Where the Food and Drug Administration is the licensing authority, the Food and Drug Administration may conduct the inspection or may accept an inspection conducted by an organization approved by the Food and Drug Administration under § 205.32.

(b) Records described in § 205.27 that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or sooner if necessitated by the duration of the inspection.

(c) Wholesale distributors must permit the appropriate Federal, or State licensing authority and State- or FDA-approved third-party inspection services to enter and inspect their premises and to audit their records and written operating procedures.

(d) To ensure compliance with this subpart, routine inspections will be conducted once every 3 years by the licensing authority, or a third-party accreditation or inspection service approved by the Food and Drug Administration or the State licensing the wholesale distributor.

§ 205.29 Requirements for initial and annual reporting to the Food and Drug Administration.

(a) *Electronic reporting requirement.* The wholesale distributor must report electronically to the Food and Drug Administration using a secure mechanism in a format the Food and Drug Administration can review, process, and archive pursuant to section 503(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Information reported will be included in the Food and Drug Administration's public database for wholesale distributors pursuant to section 503(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

(b) *Reporting periods*--(1) *Initial reporting*. Any entity that owns or operates an establishment that engages in wholesale distribution must report within 30 calendar days of obtaining an initial State or Federal wholesale distributor license.

(2) *Annual reporting.* Any entity that is licensed to engage in wholesale distribution must report to the Food and Drug Administration each calendar year between January 1 and March 31.

(c) *Required information.* Information to be reported for each wholesale distributor must include:

(1) A complete list of States where the wholesale distributor is licensed, including the corresponding identification number and the expiration date of each such license;

(2) Name of company as it appears on the license, full business address, and contact information for the facility manager or designated representative of the wholesale distributor;

(3) All trade names or business names under which the wholesale distributor conducts business; and

(4) Any significant disciplinary actions by any State or Federal Agency taken against the wholesale distributor license related to the distribution of prescription drugs, including the State where the disciplinary action occurred, date of final action, type of disciplinary action, description of the violation, and documents associated with the disciplinary action.

(d) *Timing of significant disciplinary action reporting*--(1) *Initial reporting*. The wholesale distributor must report to the Food and Drug Administration any significant disciplinary actions, including but not limited to revocation or suspension of a wholesale distributor license by a State or Federal licensing authority, which occurred in the 12 months prior to obtaining licensure.

(2) *Subsequent reporting*. The wholesale distributor must, within 30 calendar days after a final action taken by a State or Federal licensing authority, report significant disciplinary actions to the Food and Drug Administration.

(e) *Other reports*--(1) *Closure of a facility*. The wholesale distributor must report to the Food and Drug Administration that a facility has ceased operations within 30 calendar days after it has stopped operating as a wholesale distributor.

(2) *Voluntary withdrawal of a State license*. The wholesale distributor must report to the Food and Drug Administration that it has withdrawn its license in a State within 30 calendar days after such withdrawal, including any reasons for the voluntary withdrawal of licensure.

§ 205.30 Licensure denial, suspension, reinstatement, revocation, and voluntary termination--notice and opportunity to request a hearing.

(a) *Denial of application for licensure*. (1) The licensing authority will refuse to approve a wholesale distributor license application for any of the following reasons:

(i) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, are inadequate to preserve its safety, identity, strength, quality, or purity.

(ii) The facilities and controls used for the distribution of the prescription drug, including receipt, storage, and handling, are inadequate to preserve its safety, identity, strength, quality, or purity.

(iii) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, do not comply with the requirements for good storage practices in § 205.26.

(iv) The personnel employed by the applicant do not meet the requirements necessary for good storage practices in § 205.25.

(v) There is insufficient information in the written policies and procedures required under § 205.26(c) to determine whether the methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, comply with the requirements for good storage practices in § 205.26 and preserve the safety, identity, strength, quality, or purity of the prescription drug.

(vi) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, do not comply with the requirements for adequate recordkeeping in § 205.27.

(vii) The application contains an untrue statement of material fact.

(viii) The applicant does not permit a properly authorized officer or employee of the Food and Drug Administration, a State licensing authority, or an AO approved by the Food and Drug Administration pursuant to § 205.32 an adequate opportunity to inspect the facilities, controls, and any records relevant to the application.

(ix) For renewal applications, the applicant fails to report to the licensing authority any pertinent change of information required in § 205.21, § 205.22, or § 205.24.

(x) For renewal applications, the applicant fails to report to the Food and Drug Administration any of the requirements for annual reporting in § 205.29.

(2) If review of a wholesale distributor's application fails to demonstrate that the wholesale distributor meets the requirements for licensure set forth in § 205.22 and paragraph (a)(1) of this section, the licensing authority will provide written notice to the applicant that its license application may be denied, setting forth the grounds for the denial and providing an opportunity to demonstrate that the wholesale distributor meets the requirements for licensure.

(3) The notice will inform the applicant of its right to provide additional information and request reconsideration of the denial by the licensing authority within 14 calendar days of the date of the licensing authority's written notice.

(4) If no reconsideration is sought, or, if upon reconsideration, the licensing authority denies the applicant's request for licensure, the licensing authority will provide the applicant written notice of the denial and will provide the applicant notice of the opportunity to request a hearing.

(5) The applicant who wishes to request a hearing has 10 calendar days after the date of the notice of denial to submit a written notice of participation and request for a hearing. The

applicant who fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(b) *Suspension of license after notice and opportunity to request a hearing*. (1) The licensing authority may move to suspend a license if the licensing authority has a reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would likely compromise the quality of product or threaten public safety.

(2) The licensing authority will provide written notice of the intent to suspend a wholesale distributor license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate or achieve compliance. The notice will inform the applicant of its right to provide additional information, request reconsideration of the suspension by the licensing authority, and demonstrate or achieve compliance before suspension.

(3) Each wholesale distributor license holder has 30 calendar days from the date of the notice of intent to suspend to present, in writing, comments and information bearing on the initial decision.

(4) If no comments or information is received within 30 calendar days or, if upon reconsideration, the licensing authority believes the wholesale distributor license should still be suspended, the licensing authority will provide the wholesale distributor a second written notice of the intent to suspend, informing the wholesale distributor of the opportunity to request a hearing on the question of whether there are grounds for suspension.

(5) The wholesale distributor must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the notice of the intent to suspend. A

wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(7) If a wholesale distributor's license is suspended and the wholesale distributor does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(c) *Immediate suspension of license*. (1) The licensing authority may suspend a license effective immediately if the licensing authority reasonably believes that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public health.

(2) The licensing authority will provide the wholesale distributor with written notice of immediate suspension of its license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate compliance, and the opportunity to request a hearing within 10 calendar days of the wholesale distributor's request for such hearing.

(3) The wholesale distributor must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the written notice of immediate suspension. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days from the date of the written notice waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(5) If a wholesale distributor's license is suspended and the wholesale distributor does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(d) *Reinstatement of suspended licenses*. The licensing authority may reinstate a previously suspended license upon a wholesale distributor's showing of compliance with requirements in this part and upon such inspection and examination as the licensing authority may require.

(e) *Revocation.* (1) If compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(2) The licensing authority will notify the wholesale distributor of the intent to revoke the wholesale distributor's license, setting forth the grounds for the revocation and offering an opportunity to request a hearing on the proposed revocation.

(3) The wholesale distributor must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(f) *Nonrenewal*. If a license renewal application is not submitted by the date of expiration of the license, the license will be considered expired. A wholesale distributor may not engage in wholesale distribution with an expired license and must submit a new application for licensure.

(g) *Voluntary termination of licensure upon request by the wholesale distributor*. The licensing authority will terminate a wholesale distributor's license upon the wholesale distributor's request, which will include a notice of intent to discontinue prescription drug wholesale distribution and waive opportunity for a hearing. A wholesale distributor that voluntarily terminates licensure must obtain a new license before resuming wholesale distribution.

(1) If a wholesale distributor that has had its license revoked wishes to apply for a new license, the wholesale distributor must submit a new license application, which may include an inspection if required by the licensing authority under § 205.28(a).

(2) [Reserved]

Subpart D--Approved Organizations for Wholesale Distributors

§ 205.31 Use of approved third-party organizations.

(a) A third-party organization that has been approved by the Food and Drug Administration pursuant to § 205.32 ("approved organization" (AO)) may be used to conduct initial and routine inspections of the wholesale distributor's facility, as directed by the Food and Drug Administration.

(b) If an organization has been approved by the Food and Drug Administration to conduct inspections, the AO must:

(1) Complete inspections within a timeframe not to exceed 90 calendar days after receiving notice from the Food and Drug Administration to conduct an inspection;

(2) Based on the inspection, write a detailed document including a summary of the AO's findings; and

(3) Send the original document to the Food and Drug Administration, with a copy to the wholesale distributor, within 7 calendar days of completing the inspection.

(c) To become an AO, and to maintain its approval, an organization seeking the Food and Drug Administration's approval and current AOs must:

(1) Maintain records, including those that support the AO's initial and continuing qualifications for approval, for a minimum of 5 years.

(2) Maintain the following records of inspections submitted to the licensing authority for a minimum of 5 years:

(i) Copies of the records and supporting documentation reviewed as part of an inspection;

(ii) Inspection reports;

(iii) Correspondence with the Food and Drug Administration and the wholesale distributor associated with an inspection; and

(iv) Information on the identity, conflict of interest certification/compliance statement, and qualifications of all AO personnel who contributed to the inspection.

(3) Records maintained by the AO must:

(i) Be readily retrievable and made available to Federal licensing authorities upon request;

(ii) Be secure from unauthorized access or modifications; and

(iii) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(4) An AO must immediately report to the Food and Drug Administration the discovery of any evidence or observations of potential violations found at a wholesale distributor facility during an inspection of the facility that could pose imminent and serious adverse health

consequences or death to humans. Reports must be made in the manner prescribed by the Food and Drug Administration.

§ 205.32 General qualifications of approved organizations.

(a) To become and remain an AO, the organization and anyone employed by the organization, including contractors used by the organization:

(1) Must not be a current Federal or State government employee;

(2) Must not engage in prescription drug-related activities, excluding participation in the Agency's AO program and related activities, but including and not limited to manufacturing, wholesale distribution, repackaging, relabeling, dispensing, or 3PL activities;

(3) Must disclose to the Food and Drug Administration any participation or financial interest in entities that participate in the design, manufacture, promotion, or sale of articles or activities that are predominantly Food and Drug Administration-regulated or are expected to result in Food and Drug Administration-regulated articles;

(4) Must not be owned or controlled by, or have any organizational, material, or financial affiliation with, any of the entities engaged in manufacturing, wholesale distribution, repackaging, relabeling, dispensing, 3PL activities, or the design, manufacture, promotion, or sale of prescription drugs as defined in section 581(12) of the Federal Food, Drug, and Cosmetic Act;

(5) Must enter and abide by a written agreement with the applicant before data and information otherwise exempt from public disclosure may be disclosed to the AO or the contractor;

(6) Must operate in accordance with professional and ethical business practices, which include:

(i) Protecting against conflicts of interest as set forth in 5 CFR part 2635 and 18 U.S.C. 208;

(ii) Ensuring that the personnel employed or contracted by the AO who are working on inspections have sufficient education, training, knowledge, and experience to conduct inspections of wholesale distributors;

(iii) Protecting against unauthorized disclosure of nonpublic information received, records, reports, and recommendations and maintaining appropriate security and protection of such information;

(iv) Maintaining appropriate security and protection, physical and electronic, of any information received in relation to inspections;

(v) Reporting information to the Food and Drug Administration and entities for which licensure reviews were conducted that accurately reflects data reviewed, inspectional observations made, and other matters that relate to or may influence compliance with the Federal Food, Drug, and Cosmetic Act; and

(vi) Promptly responding to and attempting to resolve any complaints regarding activities for which it is approved by the Food and Drug Administration; and

(7) Must establish and maintain policies, procedures, and documentation to demonstrate that, at the time of application, and throughout their tenure as an AO, the applicant has and can continue to satisfy the requirements to qualify as an AO capable of assessing compliance with all wholesale distributor requirements. Such policies, procedures, and documentation must include, but are not limited to:

(i) AO program administration;

(ii) Disciplinary actions and corrective measures;

(iii) Recordkeeping and confidentiality;

(iv) Use of contractors; and

(v) Personnel qualifications and ongoing training.

(b) If an AO elects to use contractors for inspections, the AO remains responsible for the work of the contractors at all times.

(1) AOs that use contractors to conduct inspections must have policies and procedures in place to ensure the contractor's continuing compliance with this part, as well as competence and qualifications to conduct inspections. Such policies and procedures must ensure that contractors:

(i) Meet the qualifications set forth in paragraph (a) of this section;

(ii) Do not subcontract their inspection duties, and that contractors are removed if such requirement is violated;

(iii) Abide by the policies and procedures of the AO, as set forth in § 205.33(b); and

(iv) Complete and pass the same training required by the AO, as set forth in § 205.33(c).

(2) If an AO elects to use contractors to conduct inspections, the AO must receive and keep a record of written consent from the wholesale distributor to share confidential commercial information with contractors for which an inspection is being conducted.

(3) AOs that elect to use contractors must submit to the Food and Drug Administration a list of contractors used by the organization, accompanied by a statement from the organization certifying that such contractors meet the requirements of this subpart.

§ 205.33 Process and procedures for approval by the Food and Drug Administration.

(a) *Application.* An application to become an AO must be completed and submitted electronically to the Food and Drug Administration in a format the Food and Drug Administration can renew, process, and archive.

(b) *Required application information.* Policies, procedures, and documentation as required by § 205.32(a)(7) must accompany the application.

(c) *Training*. Organizations must provide training and any individual who conducts inspections or supervises individuals who conduct inspections is required to undergo and pass the prescribed training.

(1) If an individual does not pass training, that person must wait 30 days before retaking the training, and may be required to show proof of additional education or experiential learning to demonstrate competence before retaking the training evaluation.

(2) To maintain approval, individuals employed by the AO and conducting inspections or supervising those who conduct inspections must undergo and pass annual training as prescribed by the Food and Drug Administration. Failure to complete and pass annual training may result in suspension of approval.

(3) The Food and Drug Administration may require additional training. If such additional training is required, AOs will be given a set time period during which training must be completed and passed to maintain approval.

(d) *Auditing*. Prior to conducting its first inspection, an AO must undergo an onsite audit by the Food and Drug Administration. The Food and Drug Administration may also conduct random, periodic audits, as well as for-cause audits, of an AO, as set forth in paragraph (o) of this section.

(e) *Duration of approval and renewal process*. (1) The Food and Drug Administration approval to conduct inspections is valid for a period of 5 years.

(2) AOs must submit a renewal application to the Food and Drug Administration no later than 6 months prior to the expiration date to renew its approval.

(i) If a renewal application is submitted less than 6 months before the date of expiration, the AO's approval will expire if approval is not renewed prior to the date of expiration.

(ii) Upon expiration of the AO's approval, the AO must cease conducting any inspection-related activities.

(f) *Denial of approval*. If an organization does not meet all of the Food and Drug Administration's standards detailed in §§ 205.31 and 205.32 for becoming an AO, the Food and Drug Administration will deny the application in writing. Requests for review and reconsideration of a denial of an application must be submitted to the Food and Drug

Administration within 30 calendar days of the date of the Food and Drug Administration's decision. If, upon reconsideration, the licensing authority denies the applicant's request for approval, the licensing authority will provide the applicant written notice of the denial and an opportunity to appeal pursuant to § 10.75 of this chapter.

(g) *Suspension of approval after notice and opportunity to request a hearing*. (1) The Food and Drug Administration may suspend approval of an organization after opportunity to request a hearing when there is a reasonable probability that the organization's noncompliance will negatively impact public health.

(2) If an AO fails to maintain the Food and Drug Administration's standards pursuant to §§ 205.31 and 205.32, the Food and Drug Administration will give written notice of the intent to suspend the organization's approval, including the grounds for the suspension, and the AO will have 30 days after the date of the notice to provide additional information to the Food and Drug Administration for reconsideration.

(3) If no additional information is provided or, if upon reconsideration, the Food and Drug Administration still believes the AO's approval should be suspended, the Food and Drug Administration will issue the AO a formal written notice of intent to suspend, along with notice of the opportunity to request a hearing pursuant to part 16 of this chapter.

(4) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of intent to suspend to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days from the date of the notice waives the opportunity for a hearing.

(5) A suspended AO must notify any wholesale distributors with a pending inspection to be performed by the AO of the AO's suspension within 7 calendar days.

(h) *Immediate suspension of approval*. (1) When there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or

death to humans, the Food and Drug Administration will suspend an AO's approval effective immediately.

(2) In such a situation, the Food and Drug Administration will provide the AO a written notice of immediate suspension, along with notice and opportunity to request a hearing pursuant to part 16 of this chapter within 14 calendar days of the AO's request for such hearing.

(3) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of suspension to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(i) *Reinstatement of approval*. (1) An organization's approval may be reinstated if the Food and Drug Administration determines that the suspended organization has rectified the issues leading to the suspension and can meet the standards set forth in this subpart. Pursuant to this paragraph (i), the organization must rectify the issues and come into compliance with the Food and Drug Administration's standards within 1 year from the date of suspension. If the issues have not been rectified within 1 year, the Food and Drug Administration may revoke the AO's approval subject to the provisions of this part.

(2) An organization whose approval has been reinstated on a conditional basis will be subject to a 3-year probationary period, and if any material deficiencies arise during that period, the organization's approval may be revoked.

(j) *Revocation of approval*. (1) The Food and Drug Administration may revoke approval of an organization whose approval has been suspended pursuant to paragraphs (g) and (h) of this section:

(i) If an organization fails to demonstrate intent to comply with the issues leading to the suspension within 6 months from the date of suspension; or

(ii) If the Food and Drug Administration determines that the organization failed to rectify the issues leading to the suspension to the Agency's satisfaction within 1 year of the date of suspension.

(2) The Food and Drug Administration will give written notice of the intent to revoke the organization's approval, including the grounds for the revocation, and an opportunity to request a hearing pursuant to part 16 of this chapter.

(3) The AO must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. An AO that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) An organization whose approval is revoked that wishes to reapply to be an AO must submit a new application to the Food and Drug Administration.

(k) *Requests for reconsideration of Agency decision*. (1) The Food and Drug Administration will follow the process outlined at § 10.75 of this chapter to review matters relating to denial of approval, including review of the organization's application.

(2) The Food and Drug Administration will follow the process outlined at part 16 of this chapter to review matters relating to a suspension or revocation action, including review of the organization's application and administrative file.

(3) The Food and Drug Administration's decision after request for reconsideration of denial, suspension, or revocation constitutes a final Agency action under 5 U.S.C. 702.

(l) *Voluntary withdrawal of approval*. (1) An organization wishing to voluntarily withdraw its approval, including but not limited to when an AO goes out of business, must notify the Food and Drug Administration in writing at least 6 months prior to the date the organization intends for the withdrawal to become effective.

(i) If an AO determines it will be withdrawing its approval with the Food and Drug Administration in less than 6 months, it must notify the Food and Drug Administration

immediately of its intent to withdraw, and such notification must inform the Food and Drug Administration of the date the organization will cease business operations.

(ii) [Reserved]

(2) No later than 7 calendar days after notifying the Food and Drug Administration, the organization must notify any facilities with pending inspections that it intends to withdraw its approval with the Food and Drug Administration and must provide the date on which the withdrawal is effective.

(m) *AO-required notifications to wholesale distributors*. The AO must, within 7 calendar days of the date of suspension, revocation, or voluntary withdrawal of approval, notify those wholesale distributor facilities that have pending inspections of the AO's suspension or revocation. This notification must inform the wholesale distributor facility that it must apply for inspection with another AO, or the Food and Drug Administration if no other organization is approved.

(n) *Change of operation or ownership*. (1) The AO must report to the Food and Drug Administration within 30 calendar days any changes to the information submitted with its application for approval.

(2) Approval is not transferable.

(i) Changes in ownership of an AO require the organization to submit a new application to the Food and Drug Administration.

(ii) Such application must be submitted to the Food and Drug Administration no later than 30 calendar days prior to the date of the change of ownership.

(iii) No later than 30 calendar days before the date of the change of ownership, the AO must notify any wholesale distributor facilities with pending applications of the pending change in ownership.

(iv) On the date the change of ownership takes place, the original approval is void.

(o) *Monitoring by the Food and Drug Administration*. (1) AOs are subject to both periodic and for-cause audits by the Food and Drug Administration to ensure compliance with the Food and Drug Administration's requirements for approval in this part.

(2) If an AO refuses to cooperate with the Food and Drug Administration's audit, the organization's approval may be suspended.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

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